In the United States Court of Federal Claims

No. 01-162V
(Filed: August 11, 2009)[1]

COLTEN SNYDER, by and through KATHRYN SNYDER and JOSEPH SNYDER, his natural guardians and next friends,	*	Vaccine Act, 42 U.S.C. §§ 300aa-1 to -34; MMR and Thimerosal-Containing Vaccines; Omnibus Autism Proceeding; Role of Special Masters; Use of Three Special Masters to Hear General Causation Evidence; Admitting and Weighing Evidence; Daubert; Causation-in-Fact; Althen; Unfounded Allegations of Bias
Petitioners,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Christopher W. Wickersham, Sr., Daytona Beach, FL, with whom was Thomas B. Powers, Portland, OR, on brief and at argument, for petitioners.

Voris E. Johnson, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Judge

Petitioners seek compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2006), alleging that their son, Colten, developed a pervasive developmental disorder caused by a combination of thimerosal-containing vaccines and the Measles-Mumps-Rubella ("MMR") vaccine. This case is one of over 4,700 currently pending before the United States Court of Federal Claims' Office of Special Masters ("OSM") in the Omnibus Autism Proceeding, which was established to manage the large number of claims brought by various petitioners alleging that vaccines caused their, or their child's, autism or

[1] Vaccine Rule 18(b), located in Appendix B of the Rules of the United States Court of Federal Claims ("RCFC"), affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Because they do not object to the public disclosure of any information contained in this opinion, both parties waived the fourteen-day period in writing.

similar neurodevelopmental disorder. Moreover, it was selected to be one of three cases to test the first theory of causation advanced by the Omnibus Autism Proceeding petitioners.[2] After the Omnibus Autism Proceeding petitioners had been afforded an unprecedented amount of time to develop the evidentiary record, the special master assigned to this case, Special Master Denise K. Vowell, issued a well-reasoned, fully supported, and comprehensive decision denying–in this particular case only–entitlement to Vaccine Act compensation. Presently before the court is petitioners' motion for review of the special master's decision. For the reasons set forth below, the court sustains the ruling of the special master.

I. BACKGROUND

The special master's decision contains a thorough recitation of both the factual and procedural history of this case. See Snyder, by & Through Snyder v. Sec'y of HHS, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Thus, for context purposes only, the court presents an abbreviated version here.

A. Factual History[3]

Colten was born on January 9, 1997. Id. at *149. During the first fifteen months of his life, Colten "exhibited early signs of food allergies and asthma, in addition to a number of fevers and several gastrointestinal, respiratory, and throat infections." Id. at *150. There was "an early sign of developmental delay followed by apparently normal development" and evidence of "some behaviors that, at least in retrospect, reflect[ed] areas of concern." Id. at *149. Colten received his scheduled childhood vaccinations throughout this period.[4] Id. at *149-50 & nn.421-22.

On April 23, 1998, at age fifteen months, Colten received his first MMR vaccination during a well-child visit with his pediatrician. Id. at *151. At this visit, Colten appeared healthy and had "no signs of any receptive language disorders." Id. at *151-52. However, on May 26, 1998, after visits to the emergency room on each of the prior two days, Colten was hospitalized with "fever, diarrhea, dehydration, gastroenteritis, and pharyngitis," as well as "'mental-status

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[2] The other two cases were Cedillo v. Secretary of HHS, No. 98-916V, and Hazlehurst v. Secretary of HHS, No. 03-654V.

[3] In their motion for review, petitioners lodge no objections against the special master's recitation of Colten Snyder's medical history, diagnoses, and treatments. See Snyder, 2009 WL 332044, at *147-81 (containing sections VIII.B-C of the special master's decision). Thus, the court cites to the special master's decision rather than the underlying record.

[4] The vaccinations included those against hepatitis B; hemophilus influenzae type b ("Hib"); diphtheria, pertussis, and tetanus; and polio. Snyder, 2009 WL 332044, at *149-50 & nn.421-22. "The parties stipulated that thimerosal was present in 'preservative amounts' in the three hepatitis B vaccines and the three [Hib] vaccines Colten received . . . ." Id. at *147 n.414.

type changes.'" Id. at *153-54 (quoting the relevant medical record). On his discharge on May 28, 1998, Colten had a normal neurological examination and "was behaving in an age-appropriate manner." Id. at *155.

Between his hospitalization and his two-year well-child visit, Colten experienced several infections, in approximately the same pattern as the those he experienced prior to his MMR vaccination.[5] Id. at *156-58. In addition, at age seventeen months, one of his physicians noted that Colten had only a three-word vocabulary, and at age nineteen months, his mother noted that "he seemed to arrest his progress, and was no longer speaking well." Id. at *156, 158. In fact, at the two-year well-child visit on January 27, 1999, Colten's mother expressed "concerns regarding tantrums, discipline, and developmental milestones." Id. at *158. Colten's pediatrician "noted an avoidance of eye contact" and "right-sided weakness," causing him to refer "Colten to a pediatric neurologist and Easter Seals for motor and speech delays." Id. at *159. Colten was evaluated for his motor and speech delays on March 25, 1999, and "was recommended for psychological evaluation, an exceptional educational program, audiological evaluation, speech therapy, and parental education." Id. at *160. Colten started speech therapy and was placed on a gluten-free, casein-free diet. Id. at *161-63.

On July 28, 1999, Colten was seen by Dr. J. Jeffrey Bradstreet, id. at *163, "a family physician who has chosen to limit his practice to children with" autism spectrum disorders and attention deficit hyperactivity disorder, id. at *21. One of Dr. Bradstreet's initial diagnoses for Colten was autism. Id. at *163, 165. There is no evidence that Dr. Bradstreet used any of the accepted autism rating scales to reach this diagnosis. Id. at *163 n.467. In contrast, less than a month later, a psychologist who evaluated Colten using the Childhood Autism Rating Scale diagnosed him with a pervasive developmental disorder, albeit "not at the intensity or frequency of symptoms necessary to meet the diagnostic criteria for autistic disorder." Id. at *160. In other words, she diagnosed Colten with a pervasive developmental disorder-not otherwise specified ("PDD-NOS"). See id. at *31 ("'Pervasive Developmental Disorder' is an umbrella term for a collection of disorders. Pervasive developmental disorders include autistic disorder, Rett's disorder, childhood disintegrative disorder, Asperger's disorder, and PDD-NOS." (footnote omitted)).

Over the next eight years, Dr. Bradstreet continued to see Colten as a patient, treating him with "a wide variety of dietary supplements, secretin infusions, immunoglobulin therapy, chelation, glutathione, and prednilisone." Id. at *163 (footnote omitted); see also id. at *173-80 (describing the treatments in more detail). His recorded diagnoses varied over time, and, aside from autism, included autoimmune encephalopathy; autoimmune disease not elsewhere classified; unspecified disorder of immune mechanism; allergic gastroenteritis; autoimmune disease; unspecified urticaria; unspecified encephalopathy; gastroenteritis; colitis; disturbance of

[5] Colten also received an additional vaccination against diphtheria, pertussis, and tetanus. Snyder, 2009 WL 332044, at *147 n.414, 157. The parties "stipulated that thimerosal was not present, or present only in trace amounts," in that vaccine. Id. at *147 n.414.

sulphur-bearing amino acid metabolism; unspecified disorder of metabolism; and toxic effect of mercury and its compounds. Id. at *163. Dr. Bradstreet also ordered a wide variety of tests during his treatment of Colten, including testing for the presence of measles virus in Colten's blood, cerebrospinal fluid ("CSF"), and gut tissue. Id. See generally id. at *166-73 (describing the various tests in detail). Dr. Bradstreet sent the blood, CSF, and tissue samples to Unigenetics, a laboratory in Dublin, Ireland. Id. at *172-73. The laboratory reported that the CSF sample tested positive for measles virus, that the blood sample tested negative for measles virus, and that the gut tissue sample tested positive for the measles virus, albeit in a very low amount. Id.

In the years following his PDD-NOS diagnosis, Colten exhibited a marked improvement in his language skills. "Although Colten started the first grade classified as developmentally delayed and language impaired, at seven and one-half years of age, Colten's vocabulary and sentence structure was that of a nine year old." Id. at *165 (citation omitted). In fact, "Colten was released from the developmental delay classification on August 10, 2004." Id. Although Colten's mother attributed Colten's improvement to the treatments prescribed by Dr. Bradstreet, see generally id. at *174-80, one of respondent's experts "noted that Colten's developmental pattern was consistent with the natural history of autism" and that "Colten's normal intelligence permitted him to benefit substantially from speech and language therapy," id. at *181.

B. Procedural History

Petitioners filed a petition for compensation on March 22, 2001, alleging that Colten's April 3, 1998 MMR vaccination caused a "post-vaccinal encephalopathy." Pet. ¶ 9. The petition was filed before the July 3, 2002 creation of the Omnibus Autism Proceeding. See In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder ("Autism General Order #1"), 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002). Having clarified Colten's injury as a pervasive developmental disorder rather than the previously alleged "post-vaccinal encephalopathy,"[6] petitioners opted into the Omnibus Autism Proceeding in February 2004.

As originally contemplated, petitioners in the Omnibus Autism Proceeding would present their evidence concerning all of their causation theories in a hearing before one special master, Special Master George L. Hastings. See id. at *3. Ultimately, however, it was determined that three special masters would consider the general causation evidence for each of petitioners' theories,[7] that petitioners would identify three test cases for each theory of causation, that each of the three special masters would be assigned a test case under each theory, and that, for each test

[6] Although afforded the opportunity to do so by the special master, see Order 2, June 25, 2007, petitioners did not amend their petition to reflect the clarified injury.

[7] The other special master assigned to the Omnibus Autism Proceeding with Special Masters Vowell and Hastings was Special Master Patricia Campbell-Smith.

case, the assigned special master would apply both the general causation evidence and the case-specific evidence in rendering a decision. See Autism Master File: Notice Regarding Reassignment, Jan. 11, 2007 ("Notice Regarding Reassignment"); Autism Master File: Autism Update 4-7, Jan. 19, 2007 ("Jan. Autism Update"); Autism Master File: Autism Update 5-6, Mar. 14, 2007.[8]

The instant case was designated as the third test case for petitioners' first theory of causation ("Theory 1") in June 2007. Order 1, June 25, 2007. As alluded to above, Theory 1 posits "that a combination of the MMR vaccine and [thimerosal-containing vaccines], acting in concert, cause some [autism spectrum disorders]." Snyder, 2009 WL 332044, at *2. Shortly after the designation of this case as a test case, during a twelve-day-long hearing spanning from June 11 to June 26, 2007, all three special masters assigned to the Omnibus Autism Proceeding heard testimony concerning petitioners' first theory of causation.[9] Testimony concerning the specifics of the instant case was heard by the special master at a separate hearing conducted from November 5 to November 9, 2007.[10] After closing the evidentiary record on July 31, 2008,[11] the special master issued her decision denying entitlement to compensation under the Vaccine Act on

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[8] The Autism Master File is accessible on the website of the United States Court of Federal Claims ("Court of Federal Claims") at the following address: http://www.uscfc.uscourts.gov/node/2718.

[9] This hearing was officially conducted in the Cedillo case. Snyder, 2009 WL 332044, at *6; Autism Master File: Autism Update 3, July 12, 2007.

[10] The special master indicates that she also heard expert testimony during the hearing in the Hazlehurst case. Snyder, 2009 WL 332044, at *8.

[11] According to the special master, she considered "all of the evidence, less the medical records of the other children, introduced before, during, and after the hearings in Cedillo and Hazlehurst, as well as all of the evidence filed in this case." Snyder, 2009 WL 332044, at *7. Specifically, the evidentiary record included:

> nearly four weeks of testimony, including that offered in the Cedillo and Hazlehurst cases; over 900 medical and scientific journal articles; 50 expert reports (including several reports of witnesses who did not testify); supplemental expert reports filed by both parties post-hearing, the testimony of fact witnesses on behalf of Colten, and Colten's medical records.

Id. at *8 (footnote omitted). When citing to the record before the special master, the court prefaces the exhibit or transcript citation with the name of the case with which the evidence is associated, similar to the conventions adopted by the special master. See id. at *7-8. Also, for simplicity, citations to the corrected hearing transcripts include only the case name and page numbers.

February 12, 2009. Petitioners filed a motion for reconsideration of the special master's decision on March 13, 2009, which the special master denied on March 16, 2009. That same day, petitioners filed their motion for review, which is opposed by respondent. The court heard argument on July 29, 2009, and is now prepared to rule.

II. DISCUSSION

The Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
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> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
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> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). In the instant case, petitioners enumerate, pursuant to Vaccine Rule 24(a),[12] seven objections to the special master's decision:

1. The Use of a Panel of Three Special Masters to Hear the "General Causation" Issue in Colten's Case Was Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance With the Law;

2. The Special Masters' Decision to Allow the Last-Minute Expert Reports and Testimony of Dr. Stephen Bustin Was Arbitrary, Capricious, and an Abuse of Discretion;

3. The Special Master Abused Her Discretion by Ignoring Concessions by the Respondent's Expert Witnesses;

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[12] The Court of Federal Claims amended the Vaccine Rules effective July 13, 2009, to, among other things, bring the Vaccine Rules into conformity with the general restyling of the RCFC, see Vaccine Rules, 2009 Rules Committee Note, which the Court of Federal Claims had recently amended to conform with the general restyling of the Federal Rules of Civil Procedure, see generally RCFC, Rules Committee Notes 3 (noting that the "court has adopted a policy of regularly amending its rules to reflect parallel changes in the Federal Rules of Civil Procedure"). No substantive changes were made to any of the rules at issue here. Accordingly, except in section II.A below, all citations to and quotations from the Vaccine Rules in this opinion will be to the most recent version of the Vaccine Rules.

4. The Special Master Abused Her Discretion by Simply Ignoring Other Important Aspects of Petitioner[s'] Evidence;

5. The Special Master Abused Her Discretion by Failing to Require That Dr. Rima Disclose Underlying Data and Facts Concerning His Opinions About the Reliability of the Unigenetics Laboratory;

6. The Special Master Abused Her Discretion by Refusing to Consider Significant Post-Hearing Evidence; and

7. The Special Master's Decision Was Not in Accordance With the Law.

Pet'rs Mem. Supp. Mot. Review Special Master's Decision Feb. 12, 2009 ("Mot.") 21-61. Before turning to petitioners' numbered objections, however, the court discusses the role of special masters under the Vaccine Act, an issue implicated throughout petitioners' motion for review. It then addresses each of petitioners' numbered objections seriatim and finally concludes with some comments concerning the complaints lodged by petitioners outside of the confines of their numbered objections.

A. Role of Special Masters

As mentioned above, several of petitioners' objections to the special master's decision implicate the role of special masters in conducting proceedings and rendering decisions in Vaccine Act cases. Therefore, a discussion of their role is warranted. Congress, in creating the National Vaccine Injury Compensation Program ("Vaccine Program"), intended to address "the inadequacy–from both the perspective of vaccine-injured persons as well as vaccine manufacturers–of the current approach to compensating those who have been damaged by a vaccine . . . ." H.R. Rep. No. 99-908, at 7 (1986); accord id. at 12 (noting the twin goals of compensating those injured by vaccines without resort to a full-fledged tort system and decreasing the number of lawsuits against vaccine manufacturers). Thus, in the Vaccine Act, it crafted "a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." Id. at 1. To accomplish these aims, Congress set forth a procedure in the Vaccine Act to decide claims that placed special masters on the front lines:

> (2) A special master shall serve as an adjunct to the court and may –
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> (A) require such evidence as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided under the Program and the amount of any such compensation,

> (B) require the submission of such information as may be reasonable and necessary to determine if the petitioner is entitled to compensation,
>
> (C) require the testimony of any person and the production of any document as may be reasonable and necessary to determine if the petitioner is entitled to compensation,
>
> (D) conduct such hearings as may be appropriate, and
>
> (E) prepare and submit to the court proposed findings of fact and conclusions of law.
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> . . . . There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

Pub. L. No. 99-660, § 311(a), 100 Stat. 3743, 3761-62 (codified as amended at 42 U.S.C. § 300aa-12(d)(3)(A)-(B) (2006)). In the House Report for the underlying bill, Congress explained that because it expected a special master "to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim," discovery would be at the "prerogative" of the special master and neither party was permitted to "cross-examine witnesses, file interrogatories, or take depositions." H.R. Rep. No. 99-908, at 14-15.

Congress also specified in the Vaccine Act what matters the special master should consider in rendering a decision on a petition:[13]

> (1) In determining whether to award compensation to a petitioner under the Program, the court shall consider, in addition to all other relevant medical and scientific evidence contained in the record –
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> (A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and
>
> (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

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[13] Although Congress did not initially specify in the Vaccine Act that this section applied to the special masters, see § 311(a), 100 Stat. at 3763 (limiting the application of the section to "the court"), it soon amended the Vaccine Act to reflect the fact that this section also applied to special masters, see Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6601(j)(1), 103 Stat. 2106, 2290 (codified at 42 U.S.C. § 300aa-13(b)(1) (2006)).

> Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the court.

Id. at 3763 (codified as amended at 42 U.S.C. § 300aa-13(b)(1) (2006)). Congress elaborated in the House Report that special masters should "exercise [their] best judgment in evaluating whether the record satisfies the requirements for compensation." H.R. Rep. No. 99-908, at 18.

In 1988, Congress amended the Vaccine Act to require, as opposed to permit, special masters to "prepare and submit to the court proposed findings of fact and conclusions of law." Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 411(o)(3), 102 Stat. 683, 808. Then, in its comprehensive amendment of the Vaccine Act in 1989, Congress formally established the OSM and reiterated the special masters' duties:

> (3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall–
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> (i) include findings of fact and conclusions of law . . . .
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> . . . .
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> (B) In conducting a proceeding on a petition a special master–
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> (i) may require such evidence as may be reasonable and necessary,
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> (ii) may require the submission of such information as may be reasonable and necessary,
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> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
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> (iv) shall afford all interested persons an opportunity to submit relevant written information–
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> (I) relating to the existence of the evidence described in [42 U.S.C. § 300aa-]13(a)(1)(B), or
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> (II) relating to any allegation in a petition with respect to the matters described in section [42 U.S.C. § 300aa-]11(c)(1)(C)(ii), and

> (v) may conduct such hearings as may be reasonable and necessary.
>
> There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

Omnibus Budget Reconciliation Act of 1989 § 6601(g)(2) (codified at 42 U.S.C. § 300aa-12(d)(3) (2006)). Congress once again elaborated on the nature of the proceedings before a special master in the Conference Report for the underlying bill: "The system is intended to allow the proceedings to be conducted in what has come to be known as an 'inquisitorial' format, with the master conducting discovery (as needed), cross-examination (as needed), and investigation." H.R. Rep. No. 101-386, at 87 (1989) (Conf. Rep.). To cement the importance of the role it intended special masters to perform, Congress added teeth to the special masters' decisions, providing that the United States Claims Court ("Claims Court"), the predecessor of the Court of Federal Claims, could set aside a special master's findings of fact or conclusions of law only if they were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Omnibus Budget Reconciliation Act of 1989 § 6601(h) (codified at 42 U.S.C. § 300aa-12(e)(2)(B) (2006)). It explained that it intentionally "provided for a limited standard for appeal from the master's decision" and that it did "not intend that this procedure be used frequently but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 87.

Also among the 1989 amendments to the Vaccine Act was a provision requiring the Claims Court to promulgate rules governing proceedings on vaccine petitions consistent with the purposes of the Vaccine Program:

> (2) The special masters shall recommend rules to the Claims Court and, taking into account such recommended rules, the Claims Court shall promulgate rules pursuant to section 2071 of title 28, United States Code. Such rules shall–
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> (A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,
>
> (B) include flexible and informal standards of admissibility of evidence,
>
> (C) include the opportunity for summary judgment,
>
> (D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

> (E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Claims Court.

Omnibus Budget Reconciliation Act of 1989 § 6601(g) (codified as amended at 42 U.S.C. § 300aa-12(d)(2) (2006)).

The Claims Court complied with this directive on March 15, 1991.[14] See Rules of the United States Claims Court, App. J, 22 Cl. Ct. XXXIX, CXLVIII-CLX (1991). Vaccine Rule 3(b) set forth the duties of the special masters:

> The special master shall be responsible for conducting all proceedings, including requiring such evidence as may be appropriate, in order to prepare a decision, including findings of fact and conclusions of law, determining whether an award of compensation should be made under the Vaccine Act and the amount of any such award. The special master shall determine the nature of the proceedings with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision.

Vaccine Rule 7 reiterated that there would be "no discovery as a matter of right," and provided:

> (a) Informal Discovery Preferred. The informal and cooperative exchange of information is the ordinary and preferred practice.
>
> (b) Formal Discovery. If a party considers that informal discovery is not sufficient, that party may seek to utilize the discovery procedures provided by RUSCC 26-36 by filing a motion indicating the discovery sought and stating with particularity the reasons therefor, including an explanation as to why informal techniques have not been sufficient. Such a motion may also be made orally at a status conference.
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> (c) Subpoena. When necessary, the special master upon request by a party may instruct the clerk . . . to issue a subpoena for the taking of a deposition with or without the production of documents.

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[14] This was the second set of rules promulgated by the Claims Court for Vaccine Program cases. The first set of rules, dated January 25, 1989, was criticized by Congress as too formal. See H.R. Rep. No. 101-386, at 84 ("The Claims Court has issued rules for vaccine proceedings that force proceedings to be formal and that virtually foreclose any opportunity for petitioners or respondents to proceed without litigators at their sides."); accord id. at 86.

Vaccine Rule 8 governed the taking of evidence and argument:

> (a) General. The special master in each case, based on the specific circumstances thereof, shall determine the format for taking evidence and hearing argument. The particular format for each case will be ordered after consultation with the parties.
>
> (b) Evidence. In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties. Evidence may be taken in the form of documents, affidavits, oral testimony at a hearing in person or via telephone; or even, in appropriate circumstances, video tape. Sworn written testimony may be submitted in lieu of oral testimony.
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> (c) Argument. Argument may be received by telephone conference call or at a hearing or in written submissions. The special master may establish requirements for such filings, e.g., contents or page limitations, as appropriate.
>
> (d) Decision Without Evidentiary Hearing. The special master may decide a case on the basis of written filings without an evidentiary hearing. In addition, the special master may decide a case on summary judgment, adopting procedures set forth in RUSCC 56 modified to the needs of the case.
>
> (e) Hearing. When necessary, the special master may conduct an evidentiary hearing. The special master will determine the format for such a hearing. The special master may permit testimony at such a hearing via telephone. The special master may permit direct examination of a witness or may permit or require that the direct testimony be submitted in written form. The special master may question a witness and may, on request, permit questioning by opposing counsel. The clerk, on request, may issue a subpoena requiring the attendance of a witness at such hearing.

The remaining Vaccine Rules crafted by the Claims Court, while providing a framework for Vaccine Program proceedings, did not directly implicate the broad role of the special masters.

Although the Vaccine Act has been amended on numerous occasions since 1989,[15] at no time did Congress substantively disturb the provisions of the Vaccine Act that describe the role of special masters in the Vaccine Program–42 U.S.C. § 300aa-12(d)(3)(A)-(B) and 42 U.S.C. § 300aa-13(b)(1)–and the deference afforded the decisions of the special masters–42 U.S.C. § 300aa-12(e)(2)(B).[16] Similarly, there has been no appreciable change to the substance of the Vaccine Rules concerning the role of special masters.[17] Given these two decades of consistency in the relevant provisions of the Vaccine Act and the Vaccine Rules, it is unsurprising that the United States Court of Appeals for the Federal Circuit ("Federal Circuit") and the Court of Federal Claims have repeatedly recognized the significance of special masters in the Vaccine Program.

As early as 1991, the Federal Circuit acknowledged the congressionally mandated deferential standard of review accorded decisions of the special masters, noting that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hines ex rel. Sevier v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Indeed, held the Federal Circuit, "arguments as to the weighing of evidence, particularly where, as here, witness credibility is involved, do not demonstrate reversible error." Id. at 1527. The following year, the Federal Circuit again acknowledged the "great deference" owed the special master's findings and conclusions by a reviewing court, recognizing that "[w]ith regard to both

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[15] For example, Congress has amended the Vaccine Act to introduce a provision for suspending proceedings, to change the compensation provision, and to expand the scope of compensable injuries. See, e.g., Children's Health Act of 2000, Pub. L. No. 106-310, § 1701, 114 Stat. 1101, 1151 (codified at 42 U.S.C. § 300aa-11(c)(1)(D) (2006)); Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of 1991, Pub. L. No. 102-168, tit. II, 105 Stat. 1102, 1102-04 (codified as amended at 42 U.S.C. §§ 300aa-1, -11 to -12, -15 to -16, -19 (2006)); Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, § 5, 104 Stat. 1285, 1286-89 (codified as amended at 42 U.S.C. §§ 300aa-1, -11 to -13, -15 to -16, -21 (2006)).

[16] Sections 300aa-12(d)(3)(A) and 300aa-12(e)(2) were amended in 1992 to reflect the renaming of the Claims Court to the Court of Federal Claims. See Court of Federal Claims Technical and Procedural Improvements Act of 1992, Pub. L. No. 102-572, § 902(b), 106 Stat. 4506, 4516.

[17] The Vaccine Rules were left untouched for over a decade. On May 1, 2002, the Court of Federal Claims adopted a revised set of Vaccine Rules, leaving the substance of Vaccine Rules 3, 7, and 8 intact while making minor changes to the three rules and rearranging the order of the subsections in Vaccine Rule 8. The Court of Federal Claims amended the Vaccine Rules in 2003, 2005, and 2006, but did not make any changes to these particular rules. As noted above, the Vaccine Rules were recently restyled, but Vaccine Rules 3, 7, and 8 were not otherwise altered.

fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master." Munn v. Sec'y of HHS, 970 F.2d 863, 870-71 (Fed. Cir. 1992). Moreover, it emphasized that "the probative value of the evidence" and "the credibility of the witnesses" were within the special master's purview as fact finder. Id. at 871.

The Federal Circuit's adherence to the congressionally mandated standard of deference applicable to special masters has remained constant. For example, in Bradley ex rel. Bradley v. Secretary of HHS, it noted that the special master, as fact finder, had "broad discretion in determining credibility because [the special master] saw the witnesses and heard the testimony." 991 F.2d 1570, 1575 (Fed. Cir. 1993). Similarly, in Burns, by Burns v. Secretary of HHS, it noted both that a special master "had wide discretion in conducting the proceedings in a case" and that credibility determinations were "uniquely within the purview of the special master." 3 F.3d 415, 417 (Fed. Cir. 1993). In Hodges v. Secretary of HHS, the Federal Circuit explained:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. . . . That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

9 F.3d 958, 961 (Fed. Cir. 1993). The deference standard was reiterated by the Federal Circuit in Whitecotton, by Whitecotton v. Secretary of HHS in its remark that "Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence." 81 F.3d 1099, 1108 (Fed. Cir. 1996). And, in Lampe v. Secretary of HHS, it concluded that "[t]he arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact." 219 F.3d 1357, 1360 (Fed. Cir. 2000).

The pivotal role played by the special masters has also been recognized by the Court of Federal Claims.[18] In Sharpnack by & Through Sharpnack v. Secretary of HHS, the court recognized both the "unique role of the special master in the [Vaccine] Program" and the deference owed to the special masters' decisions. 27 Fed. Cl. 457, 459 (1993). Thus, it held that special masters had the "discretion to evaluate the utility of" a particular piece of evidence "differently in the light of all facts relevant in a specific claim," concluding that "[s]uch variations in the analyses of the special masters are within [Vaccine] Program standards." Id. at 461. In Ultimo, by Ultimo v. Secretary of HHS, the court noted that weight and credibility

[18] Prior decisions of the Court of Federal Claims, "while persuasive, do not set binding precedent for separate and distinct cases" in the Court of Federal Claims. W. Coast Gen. Corp. v. Dalton, 39 F.3d 312, 315 (Fed. Cir. 1994).

determinations are within the province of the special masters as fact finders and were, therefore, "'virtually unreviewable.'" 28 Fed. Cl. 148, 151 (1993) (quoting Hambsch v. Dep't of the Treasury, 796 F.2d 430, 436 (Fed. Cir. 1986)); accord id. ("Simply because a witness is found qualified to testify as an expert does not mean that the trier of fact must accept his testimony."); Epstein ex rel. Epstein v. Sec'y of HHS, 35 Fed. Cl. 467 (1996) (reiterating that "a determination of credibility is uniquely within the discretion of the special master"). It also remarked that it was "incumbent" upon the special master to "apply his body of knowledge . . . to the resolution of Vaccine Act cases . . . ." Ultimo, 28 Fed. Cl. at 152-53. In Lankford v. Secretary of HHS, the court concluded:

> [A] decision that reflects a reasoned evaluation of the evidence and that is otherwise free of legal error cannot be overturned. We have such a decision here. The special master confronted the task of choosing between two competing expert opinions by articulating a reasoned basis–drawn from the evidence–for preferring one over the other. No more can be demanded.

37 Fed. Cl. 723, 727 (1996) (citation omitted).

Several years later, in Sword v. United States,[19] the court expounded in detail on the role of special masters:

> As fact-finders, Special Masters, like juries, are often faced with the "battle of the experts" when it comes to interpreting facts. And as fact-finders, they may find that truth lies somewhere in between the opposing, uncompromising views of the partisan experts. Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions. However, even more than ordinary fact-finders, this Court has recognized the unique ability of Special Masters to adjudge cases in the light of their own acquired specialized knowledge and expertise. . . . The Special Master's sole professional responsibility for years has been to preside over vaccine cases . . . .
>
> . . . . No judge or jury can be forced to accept or reject an expert's opinion or a party's theory at face value. To require such a choice in this context is to neglect the Special Master's duty to "vigorously and diligently investigate the factual elements" underlying the petition.
>
> The probative value of expert testimony surfaces indirectly in providing specialized knowledge with which the fact-finder may make rational inferences

[19] Although the respondent in all Vaccine Act cases is the Secretary of the Department of Health and Human Services, 42 U.S.C. § 300aa-12(b)(1), the respondent in Sword is identified as the United States.

> and reconcile the conflicting expert opinions. A fact-finder, especially one with specialized experience such as a Special Master, can accept or reject opinion testimony, in whole or in part. When the evidence is in, and it is time to apply the facts to the law, the expert's role is over. Partisan testimony then gives way as the Special Master evaluates the testimony in light of the entire record, based on reasonable inferences born of common experience or the product of special expertise. . . . She did so in this case, weighing factors not present in the cold record–credibility and those other intangibles that lead reviewing courts to defer so greatly to the fact-finder who observed the witnesses and heard the evidence.
>
> In exercising its jurisdiction pursuant to the Vaccine Act, the Court acts not as a trial court, but as a reviewing authority. That role does not lend itself easily to resolving differing accounts of causation or other factual disputes, nor to weighing the credibility and strength of testimony. The Special Master, by contrast, heard all of the evidence first-hand and was afforded the opportunity to question the witnesses and evaluate their credibility and persuasiveness. She was, therefore, best able to steer a course through the divergent opinions in this case.

44 Fed. Cl. 183, 188-89 (1999) (citations omitted). In Ryman v. Secretary of HHS, the court explained that a special master performs a gate-keeping function "when he determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon," 65 Fed. Cl. 35, 40 (2005), but also acts as "a trier-of-fact and therefore may properly consider the credibility and applicability of medical theories," id. at 41. Finally, in Doe v. Secretary of HHS, the court stated:

> Instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions. One reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim.

76 Fed. Cl. 328, 338-39 (2007); accord Hines ex rel. Sevier v. Sec'y of HHS, 21 Cl. Ct. 634, 648 (1990) ("The Special Master is not required to be a 'potted plant' at the hearing . . . ."), aff'd, 940 F.2d at 1518.

In sum, when considering the provisions and legislative history of the Vaccine Act, the language of the Vaccine Rules, and the case law, one factor that has remained constant in the Vaccine Program is the necessary and important role of special masters in conducting proceedings and rendering decisions in Vaccine Act cases. The special masters have great leeway in how they conduct proceedings, including what evidence to consider and how to weigh that evidence, and their credibility determinations and fact-intensive conclusions are afforded great deference. However, this is not to suggest that the special masters are infallible and that their final decisions are sacrosanct. To be sure, the Court of Federal Claims on review, and the

Federal Circuit on appeal, do not merely rubber stamp special master final decisions.[20] Decisions from both courts demonstrate a willingness to reverse the decision of a special master when the special master has failed to adequately develop the record, failed to consider facts critical to the case, failed to give adequate consideration to a viable medical theory, or otherwise misapplied the law. See, e.g., Althen v. Sec'y of HHS, 418 F.3d 1274, 1276-77 (Fed. Cir. 2005) (affirming the Court of Federal Claims' reversal of the special master's decision and concluding that "the special master erred as a matter of law by imposing . . . [a] heighten[ed] . . . evidentiary burden"); Tebcherani, by Tebcherani v. Sec'y of HHS, 55 Fed. Cl. 460, 477 (2003) (finding that the special master "abused his discretion by excluding from his review the very evidence he stated was necessary to assist in determining the timing of the onset of injury"); Dickerson ex rel. Dickerson v. Sec'y of HHS, 35 Fed. Cl. 593, 601-02 (1996) (finding the special master's failure "to obtain a complete record" to be arbitrary and capricious). Nevertheless, the law is settled that neither the Court of Federal Claims nor the Federal Circuit can substitute its judgment for that of the special master merely because it might have reached a different conclusion. Reversal is appropriate only when the special master's decision is arbitrary, capricious,[21] an abuse of discretion, or not in accordance with the law.

B. Petitioners' First Numbered Objection: Using a Panel of Three Special Masters to Hear the "General Causation" Issue

The court's exploration of the role of special masters in the Vaccine Program is directly implicated in petitioners' first numbered objection. Specifically, petitioners contend that because three special masters heard all of the general causation evidence presented in Colten's case, they "had the burden of persuading not one but three special masters" that Colten's "MMR vaccine can cause autism" in violation of "the 'fundamental fairness' requirement of Vaccine Rule 8."[22]

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[20] The Federal Circuit has described the standard of review it applies in Vaccine Act cases in the following manner: "This court reviews the United States Court of Federal Claims' review of the Special Master's decision without deference." Pafford ex rel. Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing Hines, 940 F.2d at 1524).

[21] As outlined in Sharpnack, a decision is arbitrary and capricious if:

> the special master has relied on factors which Congress has not intended to be considered, or has entirely failed to consider an important aspect of the problem, or has offered an explanation of the decision that runs counter to the evidence, or is so implausible it could not be ascribed to a difference in view or a product of expertise.

27 Fed. Cl. at 459-60.

[22] The court notes that the "fundamental fairness" requirement cited by petitioners refers specifically to what evidence the special master is required to consider, and not the subsequent

Mot. 23. It is clear from the proceedings before the special masters that petitioners' contention is not supported by the record.

As noted above, it was determined that three special masters would consider the general causation evidence for Theory 1 and that each special master would then apply the general causation evidence, along with the case-specific evidence for his or her individually assigned test case, in rendering a decision. At the time that the cases were first apportioned among the three special masters, with one-third of the cases retained by Special Master Hastings and the remaining cases divided between Special Masters Vowell and Campbell-Smith, petitioners objected, "stating that 'multiple decisions by multiple Special Masters addressing nearly identical issues of law, fact, science and medicine . . . will generate significant confusion and delay at the appellate level, further slowing the progress towards resolving claims in the omnibus.'" Id. (quoting petitioners' February 26, 2007 written objection). Notwithstanding petitioners' objection, the Chief Special Master, on behalf of the OSM, explained in his Notice Regarding Reassignment that, "after much thought and discussion with the other special masters," he was assigning two additional special masters to facilitate the expeditious resolution of all of the cases in the Omnibus Autism Proceeding. Notice Regarding Reassignment 2. He noted that the final resolution of all of the cases would require rulings from the Federal Circuit because only the Federal Circuit's binding precedent could provide the OSM with the ability to resolve the cases with "speed, consistency, and certainty."[23] Id. at 1. He further explained: "The OSM is confident that the assignment of two additional special masters offers the best opportunity to resolve all of the autism cases within the shortest period of time, without negatively affecting the parties' presentation of their respective evidence and argument." Id. at 2.

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analysis of that evidence in rendering a decision. See Vaccine Rule 8(b)(1) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties."). Of course, the special masters, like all judicial officers, are required to treat all parties fairly. See, e.g., Caperton v. A.T. Massey Coal Co., 129 S. Ct. 2252, 2266 (2009) (acknowledging the "parties' basic right to a fair trial in a fair tribunal"); Day v. McDonough, 547 U.S. 198, 210 (2006) ("[B]efore acting on its own initiative, a court must accord the parties fair notice and an opportunity to present their positions.").

[23] Only decisions of the United States Supreme Court ("Supreme Court"), the Federal Circuit, the Federal Circuit's predecessor court (the United States Court of Claims), and the Court of Federal Claims in the same case on remand are binding on the special masters. See Jones v. Sec'y of HHS, 78 Fed. Cl. 403 (2007) ("The Special Master correctly concluded that he is bound by the decision of the Federal Circuit."); Hanlon ex rel. Hanlon v. Sec'y of HHS, 40 Fed. Cl. 625, 630 (1998) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand."), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

The reasoning behind the Chief Special Master's decision to assign three special masters to the Omnibus Autism Proceeding was further amplified in the January 19, 2007 Autism Update, where Special Masters Hastings, Campbell-Smith, and Vowell explained that (1) because it would be "highly unlikely that a single special master would ever be able to finally dispose of nearly 5,000 separate individual cases, . . . it seems that now is the appropriate time to get additional special masters involved"; (2) "in the overall scheme of the Vaccine Act, to have more than one special master hear the general causation evidence and offer an evaluation of the general causation issue" would alleviate concerns that "the fate of so many families would be determined based upon the analysis of a single person"; and (3) it would assist the Court of Federal Claims and the Federal Circuit "to have available the evaluations of more than one special master concerning the general causation issue." Jan. Autism Update 4-5; see also Snyder, 2009 WL 332044, at *6 ("Recognizing that special masters have authority to issue causation decisions only in the context of an individual claim for compensation under the Program and that appellate review could ensue only when an individual claim for compensation was decided, the three special masters ordered [petitioners] to identify three test cases, rather than just one, on each of the theories of causation.").

The special masters have wide discretion to conduct proceedings in a manner which, in their individual judgment, best facilitates their ability to render a decision in a particular case. See 42 U.S.C. § 300aa-12(d)(3)(B) (indicating that special masters "may" require evidence, information, testimony, or hearings, and that special masters have complete control over discovery); Vaccine Rule 8(a) ("The special master will determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties."); Burns, 3 F.3d at 417 (noting that the special master "had wide discretion in conducting the proceedings in a case"); Doe, 76 Fed. Cl. at 338-39 ("One reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim."); Sword, 44 Fed. Cl. at 190 ("On a more fundamental level, judicial officers conducting evidentiary hearings–trials–are afforded great latitude on how they administer the proceedings in their forum."). Here, the special masters determined that the interests of petitioners would best be served by having three special masters hear the general causation evidence and then apply that evidence to the individual cases. The court finds no error in that decision.[24]

Further, petitioners' contention that they were required to prove their case to all three special masters lacks merit. Although all three special masters heard and considered the general causation evidence, they issued separate decisions applying that evidence to their respective test case. See Snyder, 2009 WL 332044; Hazlehurst ex rel. Hazlehurst v. Sec'y of HHS, No. 03-

[24] The court notes that petitioners were not required to participate in the Omnibus Autism Proceeding in the first instance and that they retained the ability to withdraw their petition from the Omnibus Autism Proceeding–and proceed independently–at any time. Autism General Order #1, 2002 WL 3166785, at *6-7. Consequently, their claim of prejudice–advanced after the Theory 1 proceedings concluded and an adverse decision has been rendered–rings hollow.

654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); Cedillo ex rel. Cedillo v. Sec'y of HHS, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). The special masters were free to reach different conclusions based on the same evidence.[25] See, e.g., Sharpnack, 27 Fed. Cl. at 461 (noting that special masters had the "discretion to evaluate the utility of" evidence "differently in the light of all facts relevant in a specific claim," and that "variations in the analyses of the special masters are within [Vaccine] Program standards"); see also Hanlon, 40 Fed. Cl. at 630 (holding that special masters are not "bound by their own decisions"). That all three reached the same conclusion–rejecting petitioners' theory of causation–does not mean that petitioners were required to satisfy all three special masters. There is nothing in the record suggesting that the special masters were bound to speak with one voice. Nor can petitioners point to evidence that Special Master Vowell rendered her decision in consultation with the other two special masters. Rather, petitioners generally contend that their review of the three special masters' decisions caused them to conclude that they had to prove their individual case to all three special masters.[26] Mot. 23. The court finds no evidence in the record to support this purported heightened burden. Moreover, the decision of the special masters to conduct the general causation hearing together, rather than require three separate hearings concerning the general causation issue with the resultant duplication of the time and resources of the OSM, petitioners, and respondent, hardly suggests fundamental unfairness. To the contrary, it reflects a

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[25] For this reason, the litany of cases that petitioners recite in their motion for review for the propositions that (1) special masters in other cases have, "based on circumstantial evidence alone," established that vaccines have caused various injuries and (2) special masters in other cases have found that "[t]he MMR vaccine . . . was the legal cause of [various] off-Table neurological injuries," see Mot. 12-15 & nn.14-38, is irrelevant.

[26] At oral argument, petitioners appeared to change their argument, contending:

> I should clarify that the prejudice that was caused was primarily when there were errors . . . , th[ose] error[s] got compounded because [they] occurred in front of a panel of three. It's a bell that one cannot unring in front of three different people.
>
> And so it creates on any one individual petitioner the burden of having to then make sure . . . that the evidence that was adduced in the other cases and the procedures and the decisions in the other cases were all without error too. It compounds the burden on petitioner[s] in the presentation of evidence and it has the risk . . . of compounding and magnifying an error in one case and making it an error in the other [cases] because it all happened in front of the same group of people at the same time.

Oral Argument Tr. 15-16, July 29, 2009. However, this argument suffers from the same flaws as the argument petitioners advanced in their motion for review. If Special Master Vowell concluded that an evidentiary or procedural error had occurred, she was free to make such a ruling independent of the other two special masters when rendering her decision.

common-sense, cost-saving approach to complex litigation. Accordingly, the use of a panel of three special masters to hear the general causation evidence was not arbitrary, capricious, an abuse of discretion, or contrary to law. Petitioners' first numbered objection is rejected.

C. Petitioners' Second Numbered Objection: Allowing the Submission of Expert Reports of Dr. Stephen Bustin

In their second numbered objection, petitioners argue that the special masters, and, necessarily, the special master in this case, should not have allowed respondent's submission of two expert reports and testimony from Dr. Stephen Bustin, arguing that they were prejudiced by the "last-minute" nature of the evidence. Some procedural background is necessary to place petitioners' objection in proper context.[27]

On February 13, 2007, the three special masters set deadlines for the parties' expert reports concerning both the general causation issues and the specific causation issues in Cedillo–petitioners' expert reports were due on February 9, 2007, and respondent's expert reports were due on April 24, 2007. Snyder, 2009 WL 332044, at *22. Petitioners filed four expert reports on their deadline. Id. at *23. "After receipt of these expert reports, respondent's litigation team began identifying and interviewing potential expert witnesses. By mid-March, it became apparent that the laboratory results from Unigenetics were a key feature in petitioners' case."[28] Id. Because "Unigenetics' results were similarly important" in litigation concerning the MMR vaccine and autism spectrum disorders that had occurred in the United Kingdom ("U.K. MMR litigation"), see id. at *9 n.36, 22, in April 2007, "respondent's counsel contacted the Office of Foreign Litigation within the Department of Justice to begin efforts to obtain materials filed in the U.K. MMR litigation." Id. at *23.

On April 24, 2007, respondent filed eleven expert reports in Cedillo addressing general causation issues, including one from Dr. Brian Ward that addressed publicly available information regarding Unigenetics. Oral Argument Tr. 45. About two weeks later, Special Master Hastings directed the parties "to file all documentary evidence, including medical literature, by May 25, 2007." Id. On May 22, 2007, more than three months past their deadline and without leave of court, petitioners filed an additional expert report addressing the techniques utilized by the Unigenetics laboratory. Id. at *20, 23. On May 31, 2007, respondent filed an

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[27] It bears noting that petitioners do not dispute the special master's recitation of the following procedural history in their motion for review; in fact, they fail to mention it at all.

[28] There is no evidence in the record that petitioners dispute respondent's representation that he did not ascertain the critical role played by Unigenetics' testing in petitioners' theory of causation until he received petitioners' expert reports.

expert report prepared by Dr. Bustin that responded to petitioners' late-filed expert report.[29] Id. at *23.

In the meantime, in early May 2007, after determining that "several of petitioners' experts in Cedillo had also served as experts" in the U.K. MMR litigation, respondent "decided to attempt to obtain their reports and some evidence pertaining to Unigenetics' testing" from the court in the United Kingdom. Id. Respondent made a formal application to the High Court of Justice, Queen's Bench Division, for the release of those documents on May 18, 2007, requesting an expedited hearing. Id. Respondent informed petitioners of his application on May 22, 2007, at which time petitioners requested only that respondent share whatever he obtained from the United Kingdom court.[30] Id. at *24 & n.75. Two days later, at the May 24, 2007 hearing, the presiding jurist, the Honorable Mr. Justice Keith, expressed some concerns about the scope of respondent's request. Id. at *23. Based upon those concerns, respondent narrowed his request to "matters pertaining to [the] Unigenetics laboratory and the laboratory's testing procedures." Id. at *24. Justice Keith ruled on June 6, 2007, "that four expert reports could be released, subject to redaction of any personal claimant information." Id.; see Sayers v. SmithKline Beecham PLC, [2007] EWHC 1346 (Q.B.). One day later, on June 7, 2007, respondent filed the two expert reports from Dr. Bustin at issue here. Snyder, 2009 WL 332044, at *23-24. The hearing in Cedillo began on June 11, 2007.

Petitioners complain that the filing of Dr. Bustin's "highly technical" reports from the U.K. MMR litigation "on the eve of trial" and the submission of Dr. Bustin's "impossibly technical power-point [sic] presentation at the hearing" were "grossly unfair" because counsel for the Cedillo petitioners had "no time to review the documents, let alone prepare for cross-examination."[31] Mot. 24-25. However, petitioners could not have been surprised that respondent would need to address the laboratory results from Unigenetics–evidence that the petitioners, not respondent, put in play. As is clear from the record and as they acknowledge in their motion for review, the Unigenetics test results were "the single-most critical issue in the case." Id. at 25. This knowledge was exemplified by petitioners' filing of an expert report addressing this topic a mere twenty days before the first day of hearing. Snyder, 2009 WL 332044, at *23. Further, it

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[29] Petitioners do not object to the filing of this report in their motion for review.

[30] On this same date, respondent filed a motion to exclude all of the test results from Unigenetics, attaching to the motion affidavits from Dr. Bustin and Dr. Bertus Rima. Snyder, 2009 WL 332044, at *23. Accordingly, petitioners were notified that these two doctors "would be involved in the litigation." Oral Argument Tr. 46.

[31] At oral argument, petitioners reiterated their concern that the "11th hour late introduction of voluminous, highly technical, extremely difficult material deprived [them] of an opportunity to conduct a meaningful cross-examination." Oral Argument Tr. 6. The court notes that despite petitioners' emphasis on this issue, there is no right to cross-examination in Vaccine Program proceedings. 42 U.S.C. § 300aa-12(d)(2)(D).

was petitioners' own experts who relied upon the laboratory results from Unigenetics in rendering their opinions on causation, and whose reports alerted respondent to the importance petitioners placed on the laboratory results. Id. Indeed, Dr. Marcel Kinsbourne, petitioners' expert in pediatric neurology, testified that these test results were critical to his, and thus petitioners', theory of causation. See, e.g., id. at *78 n.234 ("[T]he validity of specific tests for measles viral material in gut tissue performed by the Unigenetics laboratory is critical to Dr. Kinsbourne's theory."), 87 (noting that Dr. Kinsbourne's opinion "rested on the actual presence of measles virus in children with [autism spectrum disorder]"), 93 ("The starting point for Dr. Kinsbourne's [theory] is inflammation caused by a persistent measles virus infection of the brain."), 194-95 (noting that Dr. Kinsbourne's causation "theory rest[ed] on one key piece of evidence: test results from a laboratory that is no longer in existence and whose practices and methods were seriously flawed"), 196 ("Absent evidence of persisting measles virus, Dr. Kinsbourne was unwilling to opine in favor of vaccine causation in Colten's case.").

Not only should petitioners not have been surprised by respondent's need to address the testing done by Unigenetics, but they were provided ample opportunity to address Dr. Bustin's expert reports in the many months following their receipt of the reports. During a June 8, 2007 status conference, the three special masters suggested, and the petitioners in the three test cases agreed, that additional proceedings could be conducted with respect to the material obtained from the U.K. MMR litigation at a later time, thus leaving the evidentiary door open. Id. at *24-25. Petitioners represented to the special masters that they intended to request additional materials from the U.K. MMR litigation not obtained by respondent. Id. at *25. The special masters and respondent agreed to join petitioners' application. Id. at *24-25. However, there is no evidence that petitioners took any action to request materials from the U.K. MMR litigation between the June 2007 hearing in Cedillo and the November 2007 hearing in Snyder.[32] Id. at *25.

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[32] At the November 2007 hearing, one of petitioners' expert witnesses, Dr. Ronald Kennedy, testified, in response to questioning by the special master, that he had not been asked by petitioners' counsel to "support the release of his own report in the U.K. MMR litigation," despite having no objections to its release. Snyder, 2009 WL 332044, at *25. Given this testimony, the special master inquired about petitioners' progress in obtaining the U.K. MMR litigation material. Id. One of petitioners' attorneys asserted "that petitioners' experts wanted to use information from the U.K. litigation, but could not obtain it." Id. On further questioning from the special master, he elaborated that petitioners' counsel "had made inquiries, but were informed by outside counsel that they could not obtain the information." Id.; accord Oral Argument Tr. 8-9 (indicating that petitioners retained a barrister in the United Kingdom to assist them). Yet, he contended, "petitioners' counsel was actively investigating what needed to be done to gain release of documents." Snyder, 2009 WL 332044, at *25. As the special master explained in her decision, this "characterization . . . of the efforts to obtain additional U.K. reports differs from the statement that appears in the notice" filed by petitioners' counsel on July 31, 2008, id. at *25 n.77, which provided: "In the period between the Cedillo and Snyder hearings, the petitioners sought, unsuccessfully, to obtain the claimant-side reports from the

At the November 2007 hearing, the special master encouraged "petitioners to proceed with speed and diligence" in their attempt to obtain the material and respondent's counsel reiterated their support of petitioners' effort. Id. at *25-26. "Between November, 2007, and July, 2008, the special masters repeatedly raised the issue of petitioners' attempts to obtain additional evidence from the U.K. MMR litigation" during status conferences. Id. at *26. They even "signed a letter indicating [their] support for release of the documents sought by petitioners." Id. Yet, "[a]t no point did" petitioners "indicate that an application had actually been made." Id. "Ultimately, based on the delay and expense that would be involved in litigating the release of some reports without the consent of the experts, [petitioners] chose not to seek the release of any of the additional expert reports." Id. Accordingly, the special master closed the evidentiary record on July 31, 2008.

Based on the preceding procedural history, it is clear to the court that petitioners have no basis to complain about the special master admitting Dr. Bustin's expert reports into the record. It was not until February 2007–when petitioners filed their expert reports–that respondent could have been aware that the test results from Unigenetics were crucial to petitioners' theory of causation. Indeed, respondent did not actually become aware of the importance of the test results until March 2007–after he retained expert witnesses to review, analyze, and respond to petitioners' expert reports. There is no question that respondent was not dilatory in obtaining as much information relevant to petitioners' theory of causation as possible prior to the Cedillo hearing in June 2007. It would have been grossly unfair to respondent had he been hampered in his ability to counter petitioners' theory of causation as a result of petitioners' failure to fully explain their theory of causation until four months before hearing, especially in light of his due diligence. It is worth remembering that in Vaccine Program proceedings, petitioners have the

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UK," Autism Master File: PSC Notice Re: UK Litigation Materials and the First Theory of General Causation 2, July 31, 2008. The special master remarked:

> This statement implied that petitioners actually made some effort to obtain the U.K. litigation materials. It was apparent to me from Dr. Kennedy's testimony that his support for release of his report had not been sought, and from the on-the-record response of counsel to my questions, that petitioners' efforts to obtain these materials had not progressed to the stage of making any application, or, indeed, anything beyond talking about the process.

Snyder, 2009 WL 332044, at *25 n.77. The special master's conclusion is buttressed by the statements made by petitioners' counsel at oral argument. Counsel stated that in order to submit an application to the court in the United Kingdom, petitioners "needed to . . . get affirmative waivers of any confidentiality from all of . . . the expert witnesses[] who participated in that litigation . . . , and we made those efforts. For different reasons, the experts whose reports we sought were not forthcoming with their permission." Oral Argument Tr. 8; see also id. at 9 (indicating that the two individuals in possession of the information they desired–Dr. John O'Leary and Dr. Orla Sheils–were nonresponsive to petitioners' requests).

burden of going forward, and only after petitioners have made a prima facie case does the burden of persuasion shift to respondent. See De Bazan v. Sec'y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Thus, without the formal discovery that is available in other civil litigation, it is not surprising that respondent in this case could not anticipate the precise nature of petitioners' theory of causation and supporting testimony.

Moreover, as previously described, the special master afforded petitioners ample opportunity to respond to the contents of Dr. Bustin's reports once the Cedillo hearing had concluded. She, along with the two other special masters, repeatedly queried petitioners about their efforts to obtain additional information from the U.K. MMR litigation, encouraged petitioners to obtain the information, and offered to join in petitioners' application for the release of the information from the court in the United Kingdom. There were almost five months between the Cedillo and Snyder hearings, eight months between the Snyder hearing and the close of the evidentiary record, and six months between the close of the evidentiary record and the special master's issuance of a decision. Thus, petitioners had approximately nineteen months within which to obtain whatever information they believed necessary to respond to Dr. Bustin's expert reports and testimony. Given this extraordinary amount of time to secure any additional information, petitioners' claim of prejudice fails. The special master's conclusion to this effect, see Snyder, 2009 WL 332044, at *27, was not arbitrary, capricious, or an abuse of discretion. Petitioners' second numbered objection is rejected.

D. Petitioners' Third and Fourth Numbered Objections: Ignoring Evidence

Petitioners next argue, in their third and fourth numbered objections, that the special master disregarded evidence relevant to their case. In their third objection, they contend that the special master "ignore[d] the many concessions of the respondents' experts,"[33] Mot. 28, including those of Drs. Diane Griffin, Brian Ward, and Robert Fujinami, as well as those related to the quality of testing by and test results from Unigenetics, id. at 28-36. In their fourth objection, they assert that the special master ignored evidence in five subject areas: reliability of test results from the Unigenetics laboratory; allelic discrimination; persistent measles virus and replication; neuroinflammation; and mercury and immune dysfunction. Id. at 36-49. Because of the overlap between the two objections, the court addresses them concurrently.

Immediately problematic is that petitioners do not explain how the special master's alleged failure to consider certain evidence would have altered her decision.[34] They allege that

[33] Petitioners' characterization of the statements as "concessions" is somewhat misleading, as it implies that the experts were admitting facts not supportive of respondent's position. As will be shown, such an implication is incorrect.

[34] Petitioners' contention at oral argument that they "outlined and explained in some detail" in their motion for review the evidence allegedly ignored by the special master, Oral Argument Tr. 16-17, is flatly untrue.

the special master disregarded evidence, but fail to explain the evidence's materiality to their case. This failure, in itself, nullifies petitioners' criticism. Yet, even presuming that petitioners' contention is that this evidence would have tipped the scales in their favor such that they would have been able to demonstrate causation by a preponderance of evidence, their contention is flawed in two respects. First, the special master's decision reflects that she carefully considered the entire voluminous record in this case. Second, petitioners fail to demonstrate that the special master improperly weighed the evidence in the record.

1. Petitioners' Theory of Causation

To place petitioners' specific contentions in context, a brief discussion of their theory of causation is appropriate. Petitioners presented their theory to the special master in the following manner:

> (1) the ethylmercury in [thimerosal-containing vaccines] is an immune suppressant; (2) the attenuated measles virus contained in the MMR vaccine is an immune suppressant; (3) the combined effect of both [thimerosal-containing vaccines] and the measles vaccine virus suppressed the immune system of at least some children who received both; (4) this immunosuppression permits the measles virus to persist in these children; (5) a persistent measles virus can enter the brain and cause a neurological injury; and (6) that neurological injury can include autism or [autism spectrum disorder] symptoms.

Snyder, 2009 WL 332044, at *28. In their motion for review, petitioners articulate how this theory of causation applies to Colten's case:

> (1) [Colten] was born healthy; (2) he had normal development and met all milestones; (3) he received all required child vaccinations, including 12 vaccines that contained ethyl mercury; (4) the mercury damaged his immune system; (5) the MMR vaccine she [sic] received at 14 [sic] months further damaged his immune system; (6) he was unable to clear the vaccine-strain [measles virus] contained in the MMR vaccine due to his immune deficiency; (7) the [measles virus] persisted and replicated in Colten; (8) the [measles virus] caused her [sic] to suffer [inflammatory bowel disease]; and (9) the [measles virus] entered his brain, causing inflammation and autism.

Mot. 17. However, as explained by the special master, the medical theory advanced by petitioners' testifying experts does not conform to this framework.[35]

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[35] Petitioners also advanced another theory of causation via the report and testimony of Dr. Jean Ronel-Corbier, a neurologist. See Snyder, 2009 WL 332044, at *12. Dr. Corbier proposed that Colten's MMR vaccination triggered an autoimmune disorder, which in turn caused Colten's autism-like symptoms. Id. at *93-94. The special master rejected Dr. Corbier's

Dr. Kinsbourne, petitioners' expert in pediatric neurology, was "the pivotal petitioners' witness on causation . . . , providing the theories upon which the causation cases were based." Snyder, 2009 WL 332044, at *11. According to the special master:

> He "connected the dots" in the general causation case among Dr. Byers' opinions on immunology and immune functioning in [autism spectrum disorder], Dr. Kennedy's opinions on virology and measles virus persistence, Dr. Krigsman's opinions on gastroenterology and gut disorders in [autism spectrum disorder], and Dr. Aposhian's opinions on mercury toxicology and the role of [thimerosal-containing vaccines] in [autism spectrum disorder].

Id. at *87. She explained Dr. Kinsbourne's hypothesis as follows:

> [D]ue to an ineffective immune response, some children with regressive autism are unable to clear the measles vaccine virus from their bodies. The virus inhabits the gut, and is transported by macrophages through the circulatory system to the brain. After crossing the blood-brain barrier, the virus invades the astroglia, neurons, and possibly microglia, invoking a response by the brain's innate immune system, the microglia. The microglia produce proinflammatory cytokines, causing brain inflammation. This inflammation disorganizes critical circuits in the brain, interrupting communication among various areas of the brain. These disorganized circuits manifest in autistic symptoms.
>
> Alternatively, or additionally, . . . the immune response to the measles virus caused gliosis, or scarring, of astrocytes (a type of glial cell sometimes referred to as astroglia). One function of astrocytes is to mop up excess glutamate at the synapses, the bridges between neurons. Damaged or destroyed astrocytes may not perform this function properly, resulting in over-activation of the brain. Excess glutamate, the brain's most prevalent excitatory neurotransmitter, can kill neurons and can cause an imbalance between excitatory and inhibitory neurotransmitters.

Id. at *77 (footnote & citations omitted). Notably, Dr. Kinsbourne "did not rely on the theory of mercury dysregulation of Colten's immune system," id. at *183, contending that the damage done to Colten's immune system was done solely by the MMR vaccine, id. at *184. In fact, the special master explained that "[t]he only witness who testified that Colten's immune system was dysregulated prior to his MMR vaccination" was Dr. Kennedy, a virologist, id. at *9, but "[w]hen informed that Dr. Bradstreet had testified that Colten's immune system was not dysregulated prior to the receipt of the MMR vaccine, Dr. Kennedy deferred to his assessment." Id. at *166 n.481. Thus, petitioners' theory of causation depended upon, among other things, Colten's

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testimony, id. at *94, and petitioners have not challenged the special master's ruling on this point.

immune system being damaged by the MMR vaccine (but not thimerosal-containing vaccines), the persistence of the measles virus in Colten's body, Colten's development of inflammatory bowel disease, and the presence of the measles virus in Colten's brain. With this background, the court proceeds to petitioners' contentions.

2. Dr. Diane Griffin

Petitioners begin by describing a number of statements that Dr. Griffin either made or with which she concurred, which the special master purportedly ignored. These statements include: (1) "measles is one of the most infectious of all viral diseases"; (2) "a 'target organ' of the measles virus is the gastrointestinal tract"; (3) "the attenuated measles vaccine can cause progressive fatal respiratory disease or neurological disease in immunocompromised individuals"; (4) "measles virus affects many components of the immune system"; (5) "measles virus causes immunosuppression that continues for months after the period of viremia"; (6) "measles virus skews T cells, and . . . when Th1 and Th2 are not in balance the body's ability to clear viruses will be impaired"; (7) "the measles vaccine, like the wild virus, causes lymphopenia"; (8) "you can definitely identify changes [in antibodies] that are occurring as part of the induction of the immune response to the vaccine"; (9) "measles can cause neurologic disease"; (10) "the risk of viral persistence increases in an immunosuppressed person"; (11) "viruses can persist in the human body"; (12) "the PCR technique used by [Unigenetics] is commonly used to detect viral RNA";[36] (13) "a measles vaccine should not be given to an immunosuppressed child";[37] and (14) "evidence of a persisting, replicating measles virus is 'an important observation' and 'should definitely be followed up' by a physician." Mot. 28-31.

Notwithstanding petitioners' representations, the special master addressed each of these assertions in her decision. See, e.g., Snyder, 2009 WL 332044, at *95 ("[Measles] is one of the most infectious viruses known. . . . It spreads to gut tissue . . . ."), 96 ("The period of immunosuppression begins at 9-15 days after exposure to the virus, and continues for approximately two to three months after recovery from measles disease."), 97 (noting a "skewing of the immune system to a Th2 response" after a measles infection), 98 (noting that "the measles vaccine virus" causes "a period of immunologic abnormalities" that are "coincident with inducing the immune response to measles"), 99 ("Following measles immunization, transient Th2 skewing occurs. . . . The vaccine virus also results in transient lymphopenia."), 105 ("Measles vaccine virus may cause or contribute to fatal respiratory or neurological disease in

[36] "PCR" is short for "polymerase chain reaction" and "is a method of exponentially replicating a strand of DNA." Snyder, 2009 WL 332044, at *110.

[37] This statement is at slight variance with the actual statement contained in the article coauthored by Dr. Griffin and cited by petitioners: "Currently, the World Health Organization and the American Academy of Pediatrics recommend [measles virus] vaccination for all HIV-infected children, except those children defined as severely immunocompromised on the basis of age-specific CD4+ T lymphocyte limits." Snyder Pet'rs Ex. 205, at 439.

severely immunocompromised recipients."), 106 ("[V]iruses persist when the host fails to form an appropriate immune response or fails to clear the virus . . . ."), 106-08 (describing the devastating, and almost always fatal, effects of the two known "diseases recognized to be associated with persistent measles virus in humans"), 107 ("[M]easles virus is known to persist only rarely . . . ."), 115 (discussing the use of PCR testing to detect measles virus RNA), 166 n.481 (noting that there was no credible testimony that Colten was immunocompromised prior to receiving his MMR vaccination). It is of no import that the special master may not have attributed the assertions to Dr. Griffin or indicated that Dr. Griffin concurred with them–it is clear that she did, in fact, consider the statements, or the underlying ideas represented by the statements.

Petitioners also allege that the special master ignored conflicting evidence from Dr. Griffin concerning whether the presence of measles virus RNA means that the measles virus is replicating.[38] Petitioners' position is that Colten's CSF contained replicating measles virus, and that an article coauthored by Dr. Griffin supports the idea that replication of the measles virus can be inferred from the presence of measles virus RNA in a tissue sample. Mot. 42-43. In that article, Dr. Griffin indicated her belief that the presence of the measles virus at multiple clinical sites in children infected with HIV represented "continued measles virus replication, not simply the persistence of measles virus RNA after the cessation of viral replication." Cedillo Pet'rs Ex. 112, tab L, at 535; accord Mot. 31, 42; cf. Mot. 36 (addressing Dr. Rima's discussion of Dr. Griffin's article). However, allege petitioners, "Dr. Griffin denied that the detection of the measles virus RNA in Michelle[Cedillo]'s gut tissue implied the presence of the protein necessary of the disease to replicate and persist, or the presence of infectious disease in Michelle . . . ." Mot. 30; accord id. at 41-42. Petitioners fail to provide any citation for this allegation, but the court will assume that they are referring to pages 2830A through 2831 of the Cedillo transcript, which contain Dr. Griffin's testimony that the replication of a virus can be inferred by the existence of an antibody reaction, something that occurs when the viral RNA makes proteins; in other words, if there is no antibody response, there are no proteins being generated by the viral RNA, and therefore there is no replication (even if the presence of viral RNA can be detected). See also Cedillo Tr. 2830A-31 (addressing the gut tissue findings for Michelle Cedillo).

As a threshold matter, the court cannot see the relevance of petitioners' contentions with respect to this issue. The special master concluded that if there indeed was measles virus RNA detected in Colten's CSF, then one must conclude that the virus had to be replicating. See, e.g., Snyder, 2009 WL 332044, at *188 ("If reliable, the report of measles virus RNA in Colten's CSF

[38] In making this argument, petitioners erroneously assert that Dr. Griffin, "[d]uring cross-examination, . . . acknowledged that she had not reviewed the Uhlmann article" that supported their claim. Mot. 42. Petitioners did not provide a citation for this testimony, and the court could locate no testimony to this effect. Indeed, Dr. Griffin's testimony strongly suggests that she had read the article, but did not have it in front of her at the hearing. See Cedillo Tr. 2834A-36, 2863, 2866. Moreover, the article is both discussed in, and attached to, Dr. Griffin's expert report. See Cedillo Resp't Ex. V. Consequently, petitioners' assertion lacks foundation.

would be strongly probative that there was an ongoing persistent measles infection in Colten's brain. If reliable, the report of measles virus RNA in Colten's gut would be probative of the "autistic enterocolitis" disease process . . . , and the gut-brain connection would provide the linkage between measles virus persisting in the gut and neurologic dysfunctions manifesting as autism."), 189 ("Measles virus, like other RNA viruses, must replicate constantly in order to survive. If no antibodies are present to fight the virus, it can replicate virtually unchecked. Thus, if measles virus were actually present in Colten's brain, but he was not manufacturing any antibodies against it, the results would be incompatible with Colten's continued life or health." (citation omitted)). Thus, she appears to concur with petitioners' position that the presence of measles virus RNA in Colten's body would demonstrate replication. Additionally, replication would only have been significant if there had been a reliable positive test result for measles virus in Colten's CSF, which, as the special master found, was not the case. See id. at *189-90.

Finally, although the special master discussed an enormous quantity of evidence in her decision, she does not appear to have specifically addressed the alleged conflict (if there is an actual conflict) between Dr. Griffin's testimony and Dr. Griffin's article. At worst, this is harmless error, especially given the special master's representation that she had considered all of the evidence in the record. See id. at *7-8. The special master was not required to discuss every piece of evidence or testimony in her decision. Maza, by Maza v. Sec'y of HHS, 67 Fed. Cl. 36, 38 (2005) ("The Special Master need not discuss every item of evidence in the record so long as her decision makes clear that she considered the petitioners' arguments."); Moreno v. Sec'y of HHS, 65 Fed. Cl. 13, 26 (2005) ("[I]t does not necessarily follow that the Special Master must issue a finding on every bit of minutiae that guides his findings as to credibility, so long as there is support in the record for his conclusions."); Snyder by Snyder v. Sec'y of HHS, 36 Fed. Cl. 461, 466 (1996) ("The special master need not discuss every item of evidence in the record so long as the decision makes clear that the special master fully considered a party's position and arguments on point."), aff'd, 117 F.3d 545 (Fed. Cir. 1997); Murphy ex rel. Murphy v. Sec'y of HHS, 23 Cl. Ct. 726, 734 n.8 (1991) ("The special master is not required to discuss every item of evidence when his decision reflects that he fully considered a party's position and arguments on point."), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992) (mem.). Nevertheless, here, the court finds no error.

3. Dr. Brian Ward

Next, petitioners claim that the special master ignored the following statements that Dr. Ward either made or with which he concurred:[39] (1) "wild measles virus causes a skewing

[39] In addition to these statements, petitioners argue that there is a conflict between Dr. Ward's testimony concerning opportunistic infections and the testimony of Dr. Ward's colleague in another case. Mot. 32 & n.51. The testimony of Dr. Ward's colleague was not before the special master, and, thus, is irrelevant here. Moreover, the testimony of that colleague coincides with what the special master expressly concluded here, that "as a general rule, if a wild-type virus can cause a problem, the vaccine virus can also cause the problem, albeit in a milder or more

towards a Th2 response, which happens to occur during the period of maximum viremia (1-2 weeks after exposure or immunization)"; (2) "skewing of the Th2 response causes immunosuppression and allows the development of opportunistic infections"; (3) "measles vaccine can cause a skewing towards a Th2 response"; (4) "measles virus can persist"; (5) "Dr. [Michael] Oldstone is one of the most respected virologists in North America[,] . . . has spent virtually his entire professional career studying viral persistence[, and] . . . has written many articles on viral persistence"; and (6) various quotations from an article written by Dr. Oldstone. Mot. 31-33.

As with the statements made, or agreed to, by Dr. Griffin, the special master addressed each of these topics in her decision. See, e.g., Snyder, 2009 WL 332044, at *10 (noting that Dr. Oldstone was a "widely recognized expert in virology and in the study of measles"), 96 ("In measles infections, the immune system is actively involved in fighting the measles virus, and does not respond normally to other pathogens. Thus, most measles-related deaths are the result of . . . opportunistic infections, rather than from the measles disease itself."), 97 ("The time frame in which the Th2-deviated response occurs would roughly correspond to the period of maximum viremia after infection with the measles virus."), 99 ("Following measles immunization, transient Th2 skewing occurs."), 104 ("The skin rash occurs between nine and fifteen days after infection, marking the peak level of virus in the body, known as the period of maximum viremia."), 106 ("[T]he diseases caused by replicating viruses are often new and unexpected."), 106 & nn.337-38 (citing Dr. Ward for the fact that "Dr. Michael Oldstone [is] one of the world's most highly regarded virologists" and discussing petitioners' reliance upon an article written by Dr. Oldstone), 107 ("[M]easles virus is known to persist only rarely . . . ."). Again, it is of no import that the special master may not have attributed these assertions to Dr. Ward or indicated that Dr. Ward concurred with them–it is clear that she did not ignore the statements, or the underlying ideas represented by the statements.

4. Dr. Robert Fujinami

Petitioners next argue that the special master ignored evidence supplied by Dr. Fujinami. As a preliminary matter, petitioners complain that because respondent failed to call Dr. Fujinami to testify, they lacked any opportunity to cross-examine him on the contents of his expert report.[40] Mot. 33-34. However, the special master clearly stated that because Dr. Fujinami, an immunologist, did not testify, she "relied on his report primarily for background information on immunology not supplied by" one of petitioners' immunologists. Snyder, 2009 WL 332044, at *16. Petitioners then claim that Dr. Fujinami nevertheless "provided significant evidence in support of [Colten's] case." Mot. 34. It was so significant that petitioners needed just one

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attenuated form." Snyder, 2009 WL 332044, at *99; accord id. at *104. Thus, petitioners' argument lacks merit.

[40] Once again, the court notes that Congress has expressly determined that there is no right to cross-examination in Vaccine Program proceedings. 42 U.S.C. § 300aa-12(d)(2)(D).

sentence to describe it: "[Dr. Fujinami] has known for decades . . . that measles virus can persist in human cells, injure tissues, and cause a potentially damaging autoimmune response." Id. (citing Cedillo Pet'rs Ex. 132). Indeed, petitioners do not even attempt to explain the significance of the article or how the article applies to Colten's case. Had the article been as valuable to petitioners' case as they claim, surely they would have sought to subpoena Dr. Fujinami's testimony or retain his services.

5. Unigenetics

Petitioners next allege that the special master ignored a plethora of evidence concerning the reliability of test results from Unigenetics. As a preface to addressing petitioners' contentions, a brief summary of the special master's conclusions on this topic is in order. As alluded to above, respondent mounted a vigorous attack against the reliability of the laboratory results from Unigenetics. The evidence regarding the laboratory's reliability came from both publicly available information and documents obtained from the U.K. MMR litigation. Snyder, 2009 WL 332044, at *116. Because the petitioners in Cedillo and Hazlehurst moved to strike the evidence derived from the U.K. MMR litigation,[41] the special master, out of an abundance of caution, split her analysis of the laboratory's reliability into two parts, and concluded:

> [A]n analysis of the public evidence alone clearly demonstrates that the results from Unigenetics cannot be relied upon as evidence of the persistence of measles virus in children with autism. When considering the U.K. litigation information, the evidence that Unigenetics' results are not reliable is overwhelming. Unigenetics' operations reflect unsound applications of the sound scientific process of PCR testing.

Id. (emphasis added); accord id. at *189. Accordingly, the special master's consideration of the U.K. MMR litigation documents forms the basis for an alternative holding; her conclusion that the laboratory results from Unigenetics were unreliable does not depend on them. Petitioners' assertions concerning the evidence regarding the reliability of the Unigenetics laboratory results described below implicate both of the special master's holdings.

a. Dr. Stephen Bustin

Petitioners' first contention to support the reliability of the laboratory results from Unigenetics centers upon the copy numbers derived during its PCR testing and Dr. Bustin's opinion relative to those copy numbers. As explained by the special master, PCR testing "is a method of exponentially replicating a strand of DNA," where "extremely small quantities of DNA can be amplified, creating enough DNA to produce a visible 'band' on a gel." Id. at *110. Specifically, a primer (i.e., a complementary strand of DNA) is selected, the target strand DNA is split by heating, and a polymerase is added, all resulting in the formation of two strands of DNA

[41] No formal motion was filed in the instant case. Snyder, 2009 WL 332044, at *27, 116.

from the original single strand. Id. at *111. This process constitutes one PCR testing cycle. Id. "A second cycle increases the two strands to four by heating the DNA to induce splitting, and reforming each of the split strands by the added polymerase. A third cycle turns the four strands into eight, and the process proceeds exponentially, normally through 20 to 40 cycles . . . ." Id. Thus, when the PCR testing on a target strand of DNA has concluded, the laboratory performing the test would know how many copies of the DNA were made and how many cycles of testing were required to make that number of copies. To demonstrate the existence of a particular DNA molecule in a sample, the optimal result would combine a high copy number and a low number of cycles. See generally id. passim.

Petitioners generally assert that the special master ignored testimony from Dr. Bustin that suggested that his lone objection to the results from Unigenetics was to the low copy numbers. Mot. 34-37. In making this contention, petitioners aver: "High copy numbers are considered accurate because the detection of RNA occurs at a lower cycle number, in other words, earlier in the experiment, and makes them inherently reliable." Id. at 34-35; accord id. at 37. However, the special master, citing various portions of hearing testimony, expressly noted that "[e]ven when the copy numbers were high, the high values could reflect contamination rather than high amounts of the target substance in tissue" and that "[a] high copy number of measles virus does not necessarily imply that the threshold cycle (CT) was low." Snyder, 2009 WL 332044, at *135. Although they acknowledge Dr. Bustin's testimony that a high copy number could reflect contamination, petitioners contend that the special master ignored the contrary testimony of Dr. Karin Hepner.[42] Mot. 39. This contention is demonstrably false.[43] See Snyder, 2009 WL

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[42] In her alternative reliability analysis that addressed the publicly available information concerning Unigenetics along with the information obtained from the U.K. MMR litigation, the special master addressed Dr. Hepner's independent research referenced by petitioners in their motion for review. See Snyder, 2009 WL 332044, at *135-36 (containing a section titled "6. The Walker-Hepner 'Poster Presentation.'"); Mot. 39 (noting that Dr. Hepner "has herself replicated the [Unigenetics] lab's findings"). Given the preliminary, unpublished nature of Dr. Hepner's data, among other issues, the special master did not credit it. See Snyder, 2009 WL 332044, at *135-36.

[43] Further, to the extent that petitioners are contending that Dr. Bustin's "dispute was only with [Unigenetics'] low copy numbers," Mot. 35 (citing Cedillo Tr. 2042); accord id. at 36 (citing Cedillo Tr. 2045[A]), to the exclusion of any other criticism of Unigenetics, their contention is erroneous. It is apparent from his testimony that Dr. Bustin had concerns about Unigenetics' low copy numbers, high cycle numbers, and standard curve. See, e.g., Cedillo Tr. 2040 (indicating that "there is a problem with the low copy numbers and the higher cycle numbers"), 2045A (indicating that Dr. Bustin's "concern really is with low copy numbers and high cycles, high number of runs"), 2062A-65A (explaining his problems with Unigenetics' standard curve). It was petitioners' expert, Dr. Kennedy, who testified: "I think the issue was that no one had any problem with high copy numbers." Snyder Tr. 337A; see also Snyder, 2009 WL 332044, at *117 ("Doctor Kennedy testified that, at least with the high copy number results,

332044, at *117 ("Based on the high copy numbers of measles virus RNA found in some of the samples, [Dr. Hepner] concluded that the positive findings were not artifacts and represented actual virus detection."), 135 (discussing Dr. Hepner's challenge to Dr. Bustin's "testimony that high copy number samples could be the product of 'spontaneous' contamination"). Moreover, the special master discussed Unigenetics' copy numbers within her alternative analysis, which addressed the publicly available information concerning Unigenetics along with the information obtained from the U.K. MMR litigation. See id. at *134-35. Thus, to the extent that there is error in the special master's analysis, such error would be harmless because her primary reliability holding excluded, and thus there was no reliance upon, the U.K. MMR litigation evidence.

Petitioners also assert that the special master disregarded Dr. Bustin's hearing testimony about Dr. Finbar Cotter's effort to replicate Unigenetics' results, including his ability to replicate results at high copy numbers, which they assert proves that the results were reliable. Mot. 34-35, 38-39. First, the special master clearly addressed this evidence–she devoted an entire section to it. See Snyder, 2009 WL 332044, at *132-33 (containing a section titled "(6) Reproducibility of Unigenetics' Results in U.K. MMR Litigation"). Second, because Dr. Cotter's testing was performed "within the context of the U.K. MMR litigation," the special master considered this testimony within her alternative analysis, which addressed the publicly available information concerning Unigenetics along with the information derived from the U.K. MMR litigation. See id. Thus, to the extent that there is error in the special master's analysis, such error would be harmless because her primary reliability holding excluded, and thus there was no reliance upon, the U.K. MMR litigation evidence.[44]

Finally, petitioners claim that the special master ignored the limited utility of the laboratory notebooks from Unigenetics relied upon by Dr. Bustin.[45] Mot. 26, 37. However, the

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he considered the Unigenetics' results to be reliable."). As an aside, petitioners attributed the following assertion to Dr. Kennedy: "[T]he group of scientists who studied the discrepancies between the labs unanimously concluded that [Unigenetics'] findings with respect to high copy numbers were absolutely reliable." Mot. 39 (citing Snyder Tr. 346[A]). The testimony cited by petitioners, however, does not appear to conform with their representation.

[44] Accordingly, it is of absolutely no import that "Colten, of course, had no access to this allegedly 'sealed' evidence from the UK litigation." Mot. 38 n.57. Moreover, as described elsewhere in this opinion, the special master concluded that petitioners' lack of access was a problem of their own making.

[45] In raising this concern, petitioners accuse the special master of making the "preposterous conclusion" that Dr. Bustin's testimony reflected that contamination in the Unigenetics laboratory was "'rampart'[sic]." Mot. 37-38 n.56. Assuming that petitioners meant "rampant," their claim is baseless. Nowhere does the special master describe contamination in the Unigenetics laboratory as rampant. Petitioners may instead be referring to the decision of

special master addressed the notebook data in her decision. See, e.g., Snyder, 2009 WL 332044, at *130-31. Moreover, her discussion of the notebook data fell within her alternative analysis that combined the publicly available information concerning Unigenetics with the material derived from the U.K. MMR litigation. See id. Thus, to the extent that there is error in the special master's analysis, such error would be harmless because her primary reliability holding excluded, and thus there was no reliance upon, the U.K. MMR litigation evidence.

b. Dr. Michael Oldstone

Next, petitioners contend that the special master disregarded the contents of a letter authored by Dr. Oldstone, which they claim supports their case. Mot. 35. In fact, Dr. Oldstone wrote the letter to counter petitioners' reliance on his research and to explain his experience with Unigenetics. Thus, petitioners' complaint lacks merit on several grounds. First, petitioners' contention that the special master ignored the letter is entirely inaccurate, as she clearly discussed both aspects of Dr. Oldstone's letter in her decision. See Snyder, 2009 WL 332044, at *106 (discussing petitioners' reliance on Dr. Oldstone's research), 123-24 (containing a section titled "(5) Doctor Oldstone's Experience"). Second, petitioners, through the use of selective quotation, completely misrepresent the contents of the letter. Petitioners represent that Dr. Oldstone's letter reflects his belief in the reliability of results from Unigenetics, characterizing his view as follows:

> In his letter, Dr. Oldstone revealed "[i]n the early 2000s" he reviewed the [Unigenetics laboratory's] protocols for detecting measles virus with PCR, and found them "to be sound." In addition, Dr. Oldstone stated, [Unigenetics'] test results agreed with his own in 80% of the samples he sent to the [Unigenetics] lab.

Mot. 35 (citation omitted). Standing in stark contrast to petitioners' characterization are Dr. Oldstone's own words. According to Dr. Oldstone, when he first received the results from Unigenetics, he "discovered that approximately 20% of the samples were incorrect as to the presence or absence of measles." Snyder Resp't Ex. AA. Nevertheless, because Dr. Oldstone found the testing protocols "to be sound," he sent another batch of samples to the laboratory for testing. With respect to the second set of results, he found:

Special Master Hastings in Cedillo, where, in the course of describing the evidence presented concerning Unigenetics, he stated: "But when Dr. Bustin closely examined the results of the Uhlmann study, he found that in approximately one-third of Unigenetics' testing procedures ('runs'), the lab obtained positive results for their negative controls. Dr. Bustin testified that this result meant that contamination was rampant in the Unigenetics lab." Cedillo, 2009 WL 331968, at *36 (citing Cedillo Tr. 1995-96 (containing Dr. Bustin's testimony that "the presence of contamination in one-third of your assays suggests they have a significant contamination problem")).

> The results of the second round were no better with again approximately 20% of the samples misidentified . . . .[46] Most troublesome, some samples, when tested twice under different code numbers[,] 'switched' from positive to negative or from negative to positive. On the basis of the inaccuracies of their PCR test, I declined from further working with [Unigenetics].

Id. (footnote & emphasis added). Thus, it is clear that the results from the second round of testing caused Dr. Oldstone to lose faith in the soundness and reliability of testing done by Unigenetics.[47]

Most egregious is petitioners' suggestion that Dr. Oldstone's letter included statements not actually contained in the letter. They assert: "Dr. Oldstone also indicated that there was concordance between the two laboratories on high copy numbers. In other words, the high copy numbers detected by the [Unigenetics] primers were confirmed by the Oldstone laboratory using its primers." Mot. 35; accord id. at 40. Nothing in Dr. Oldstone's letter even approximates this assertion, and petitioners provide no citation to the record where it might otherwise be located.[48]

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[46] In this vein, Dr. Ward testified that an eighty percent concordance rate "would be unacceptable in a research setting, and was wildly inappropriate for a diagnostic lab, such as Unigenetics." Snyder, 2009 WL 332044, at *123.

[47] At oral argument, petitioners changed tack. Rather than arguing that the contents of Dr. Oldstone's letter supported their position, they averred that Dr. Oldstone must have been the source of the twenty percent rate of misidentification. See Oral Argument Tr. 20 ("Dr. Kennedy testified that it was just as likely that the reason for the inconsistent results between Dr. Oldstone's lab and [Unigenetics] was that the samples were misidentified as to whether they were positive or negative to begin with."). Petitioners further claimed that "the special master . . . just adopted the conclusion of Dr. Oldstone and frankly ignored significant testimony, particularly from Dr. Kennedy, that the claimed errors of Dr. Oldstone actually were errors that occurred in Dr. Oldstone's lab . . . ." Id. Petitioners are incorrect. The special master addressed, and then, as was in her discretion, discounted Dr. Kennedy's testimony. See Snyder, 2009 WL 332044, at *124 ("Although it is possible that contamination of the samples submitted occurred in Dr. Oldstone's laboratory, a position advanced by Dr. Kennedy, Dr. Ward discounted that possibility. . . . Doctor Kennedy also suggested the misidentified samples were probably at the low end of the detection threshold, but his explanation did not account for false positive results nor how the same samples could test positive initially, but negative when submitted a second time, or vice versa." (citations omitted)).

[48] Dr. Ward's testimony about his conversation with Dr. Oldstone that led to Dr. Oldstone's preparation of the letter similarly lacks support for this statement. See Snyder Tr. 952A-62A (direct testimony), 983A-91 (cross-examination). However, Dr. Kennedy's testimony, although unclear, might conceivably provide support for the statement. See id. at 337A-339A (suggesting that Dr. Oldstone had obtained high copy numbers from the technique he

Similarly, petitioners indicate that "the Oldstone laboratory did replicate the [Unigenetics] lab's results with respect to high copy numbers." Id. at 38. Petitioners fail to cite, and the court could not find, evidence in the record that Dr. Oldstone attempted to replicate Unigenetics' test results.

c. Dr. Bertus Rima

Petitioners' next contentions concern the testimony of Dr. Rima. They first claim that the special master ignored testimony that countered Dr. Rima's assertion, repeated by Dr. Griffin and described by the special master, that the "extremely high copy numbers" of measles RNA found in Colten's CSF "were not biologically plausible." Snyder, 2009 WL 332044, at *190. According to petitioners, Dr. Kennedy testified to a plausible explanation for the high copy numbers with which neither Dr. Rima nor Dr. Griffin disagreed. Mot. 40. However, there is no question that the special master considered the issue of copy numbers that were too high and found the testimony of respondent's experts to be more persuasive. See, e.g., Snyder, 2009 WL 332044, at *190.

Petitioners also claim that the special master disregarded Dr. Rima's testimony concerning both measles virus replication and Unigenetics' use of immunohistochemistry. Mot. 35-36; cf. id. at 42 (describing Dr. Griffin's lack of awareness of the alleged immunohistochemical testing). Once again, the special master discussed both of these topics in her decision. See, e.g., Snyder, 2009 WL 332044, at *95 ("The measles virus is a single-stranded RNA virus. RNA viruses are unstable, and need to replicate constantly in order to maintain themselves." (footnote & citations omitted)), 95 n.299 (noting "Dr. Rima's testimony that the virus must continue to replicate in order to survive"), 106-07 (indicating that in cases of subacute sclerosing panencephalitis ("SSPE"), the measles virus persists and replicates for seven to ten years after infection), 109 n.350 (discussing the conflicting evidence about whether Unigenetics performed immunohistochemical testing), 117 & n.356 (discussing the Uhlmann paper and its ambiguous reference to immunohistochemical testing). It does not matter that the special master may not have attributed the assertions to Dr. Rima or indicated that Dr. Rima concurred with them–it is clear that she considered the statements, or the underlying ideas represented by the statements.

Finally, petitioners insist that the special master ignored both Dr. Rima's testimony and their own "direct evidence" that Unigenetics used allelic discrimination to positively identify vaccine strain measles RNA in Colten's samples.[49] Mot. 35-36, 41. Petitioners are mistaken.

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used, but expressing uncertainty regarding whether Dr. Oldstone used the same PCR technique as Unigenetics).

[49] Petitioners cite "Pet. Ex. 150" as the source of their "direct evidence," Mot. 41, but no such exhibit exists in the record. The court presumes that petitioners meant to cite Cedillo Petitioners' Exhibit 130. See id. at 36 n.53. This exhibit contains a brief synopsis of a paper titled "Development of an 'allelic discrimination' type assay to differentiate between the strain

The special master devoted an entire section of her decision to allelic discrimination, which included a description of Dr. Rima's testimony concerning the Unigenetics test results. See Snyder, 2009 WL 332044, at *133-34 (containing a section titled "(7) Sequencing and Allelic Discrimination," which contains four paragraphs discussing Dr. Rima's testimony). Moreover, to the extent that petitioners are complaining that the special master did not explicitly cite the five-paragraph, eleven-sentence paper synopsis constituting their "direct evidence," the court notes that the special master indicated that Unigenetics' allelic discrimination test results, as described in the synopsis, "were never published," id. at *134, strongly suggesting that she considered it. The court reiterates that the special master was not required to refer to every piece of evidence in her decision. Maza, 67 Fed. Cl. at 38; Moreno, 65 Fed. Cl. at 26; Snyder, 36 Fed. Cl. at 466; Murphy, 23 Cl. Ct. at 734 n.8.

d. General Statements about PCR tests

Finally, petitioners briefly argue that the special master ignored evidence regarding proper PCR testing procedures, including the use of controls, the prevention of contamination, and the prevalence of contamination. Mot. 37-38. This is obviously not the case. The special master carefully described how PCR testing is performed, and addressed both controls and contamination extensively. See, e.g., Snyder, 2009 WL 332044, at *110-15 (containing a detailed section titled "3. Polymerase Chain Reaction," describing how the test is performed, how the results are confirmed, and typical problems with the test), 114 ("Contamination is frequent even in the most compulsively monitored laboratories."), 116-36 (applying the discussion of PCR testing to the Unigenetics results).

Altogether, there is no indication that the special master ignored the evidence cited by petitioners regarding the reliability of the test results from Unigenetics when rendering her decision.

6. Neuroinflammation

Petitioners next contend that the special master disregarded evidence demonstrating that measles caused Colten's neuroinflammation. Mot. 43-46. Initially, petitioners recite various facts about encephalitis–i.e., inflammation of the brain–demonstrating that it has occurred as both a result of persistent measles infection and following MMR vaccination. Id. at 43-44. Notwithstanding petitioners' representations, all of these facts were recognized by the special master in her decision. See, e.g., Snyder, 2009 WL 332044, at *99 ("The Vaccine Injury Table recognizes that the measles vaccine can cause . . . encephalopathy or encephalitis . . . ."), 104 (indicating that "anything that the wild-type virus can cause can also be caused by the vaccine strain virus"), 106-08 (discussing SSPE and measles inclusion body encephalitis). In spite of the

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origins of measles virus detected in intestinal tissue of children with ileocolonic lymphonodular hyperplasia and concomitant developmental disorder.'" Cedillo Pet'rs Ex. 130. The underlying paper, if it exists, was not submitted into evidence.

special master's obvious recognition of these facts, petitioners contend, without supplying a citation, that "it is difficult to fathom how the special master could state that it is unproven that measles can cause neuroinflammation." Mot. 44. The special master never made such a statement, but rather held that petitioners had not demonstrated that the measles virus could cause neuroinflammation in individuals with autism spectrum disorder, Snyder, 2009 WL 332044, at *87-89 (discussing "Stage 1" of Dr. Kinsbourne's theory), 94 ("[T]here is no evidence the measles virus causes inflammation or any other brain pathology found on autopsy of [autism spectrum disorder] patients."), or that the measles virus caused neuroinflammation in Colten, id. at *181-83 (rejecting Dr. Bradstreet's assertion that Colten suffered from a "'measles virus induced encephalopathy from persistence of the measles virus in his [central nervous system].'").

Petitioners also argue that the special master ignored the contents of an article written by Dr. Oldstone. Mot. 44-46. They never explain the relevance of this article to neuroinflammation, and none of the quotations they provide discuss neuroinflammation. To the extent that the article is relevant to the issue at hand, there is no question that the special master read and considered the article. See, e.g., Snyder, 2009 WL 332044, at *106 (noting that Dr. Oldstone's article was "read repeatedly into the record" and that "the general statements" in the article "hardly constitute evidence that the measles virus actually persists to cause autism").

7. Mercury and Immune System Dysfunction

Petitioners' final allegations that the special master disregarded evidence concern the relationship between mercury and immune system dysfunction. Mot. 46-49. In this regard, they make the following claims: (1) petitioners "relied on evidence presented in Cedillo that the mercury contained in numerous vaccines received by Colten affected his immune system and allowed measles to persist in his CSF long after it should have been eliminated from his body"; (2) the special master found that petitioners had not demonstrated "mercury induced immune dysfunction" in Colten's case; and (3) the special master ignored the evidence that contradicted this finding. Id. at 46. All three claims are flawed.[50]

With respect to petitioners' first claim, the special master found no credible evidence that Colten's immune system was dysregulated prior to receiving the MMR vaccination. See Snyder, 2009 WL 332044, at *166 n.481. Additionally, petitioners' main expert on causation, Dr. Kinsbourne, "did not rely on the theory of mercury dysregulation of Colten's immune system," and instead contended that the damage done to Colten's immune system was done by the MMR vaccine. Id. at *183-84. And, the special master concluded that there was no "excess mercury in

[50] Petitioners also claim that the special master disregarded "the vast body of evidence regarding the effects of mercury on the immune system, and then declare[d] that petitioner had failed to prove that mercury exposure can lead to a dysfunctional immune system." Mot. 49. This claim is similarly flawed. The special master devoted an entire section of her decision to the effects of mercury on the immune system. See Snyder, 2009 WL 332044, at *72-76 (containing a section titled "a. Immune Systems Effects").

Colten's body." Id. at *169. None of these findings is contested by petitioners. Thus, petitioners' reliance upon the effect of the mercury contained in the vaccines received by Colten is misplaced. They have no basis to assert that "the mercury contained in numerous vaccines received by Colten affected his immune system . . . ." Mot. 46.

The flaws in petitioners' second claim flow directly from the flaws in their first. Petitioners did not advance a theory of "mercury induced immune dysfunction" in Colten's case. See Snyder, 2009 WL 332044, at *183-84. Therefore, the special master had no obligation to make such a finding.[51] Similarly, because the special master was not obligated to consider an argument that was not advanced by petitioners, she could not have ignored evidence related to that argument, as petitioners aver in their third claim. Moreover, the subject matter of the evidence described by petitioners that the special master supposedly ignored–testimony of and literature cited by Dr. Jeffrey Brent, a medical toxicologist, id. at *19-20, about the effect of mercury on the immune system–was given an in-depth treatment by the special master in her decision, despite its ultimate irrelevance. See id. at *72-76.

8. Conclusion Regarding Petitioners' Third and Fourth Numbered Objections

In sum, far from disregarding the statements and various subject matter cited by petitioners, the special master both considered them and assigned them the weight that she felt appropriate.[52] See Hodges, 9 F.3d at 961 n.4 ("Clearly the Special Master evaluated petitioner's evidence . . . in light of the facts of the case. That [s]he judged it to fall short of proving the case by the standard the law requires is not the same as refusing to consider it."). Although they never expressly discuss the materiality of these statements, it is apparent that petitioners' grievance is

[51] Indeed, because of Dr. Kinsbourne's position that "causation in Colten's case did not depend on any form of immune dysregulation predating Colten's [MMR] vaccination," Snyder, 2009 WL 332044, at *183, the special master properly limited her analysis to any immune dysfunction caused by the MMR vaccine, see, e.g., id. at *185-86 (discussing Colten's alleged immune system dysfunction and concluding that "[t]he evidence that Colten's immune system was 'dysregulated' after his MMR vaccination is unconvincing").

[52] As was made clear in the court's analysis, the representations made by petitioners in their third and fourth numbered objections were almost wholly without a factual basis. Indeed, in several instances, petitioners were clearly attempting to mislead the court. See Mot. 31 (misrepresenting the contents of one of Dr. Griffin's articles), 34 (contending that Dr. Fujinami provided "significant evidence" but describing the evidence in one, general sentence and failing to actually explain the significance), 35 (misrepresenting Dr. Bustin's testimony and the contents of Dr. Oldstone's letter), 42 (misrepresenting whether Dr. Griffin had reviewed the Uhlmann article).

that the special master did not find petitioners' expert testimony persuasive.[53] However, the weight accorded such evidence is within the sound discretion of the special master. Lampe, 219 F.3d at 1360; Whitecotton, 81 F.3d at 1108; Munn, 970 F.2d at 871; Hines, 940 F.2d at 1527. Because the special master did not abuse her discretion, the court will not disturb those findings. Petitioners' third and fourth numbered objections are rejected.

E. Petitioners' Fifth Numbered Objection: Failing to Require That Dr. Rima Disclose Underlying Data and Facts Concerning His Opinions

In their fifth numbered objection, petitioners argue that the special master improperly "allowed Dr. Rima's opinion testimony concerning the reliability of the Unigenetics Laboratory without also requiring that he disclose the underlying facts and data he relied on." Mot. 50. Petitioners explain that Dr. Rima's expert testimony "was informed, in large part, by what he described as his review of laboratory notebooks, logs, and data generated in the course of work by Unigenetics and made available to him to examine in the United Kingdom," but that these documents and data were not disclosed to them before or during Dr. Rima's testimony. Id. Petitioners make two broad contentions: first, that the special master should have applied the general framework of the rules of evidence and civil procedure to exclude Dr. Rima's testimony, and second, that they did not waive their objection to the use of Dr. Rima's expert report and testimony. Id. at 51-54.

As a threshold matter, the court would be remiss if it did not highlight the fatal flaw in petitioners' argument. As noted above, the special master concluded that Unigenetics' results were unreliable, reaching that conclusion using two different analyses: the first by considering only the publicly available evidence and the second by adding consideration of the evidence derived from the U.K. MMR litigation. See Snyder, 2009 WL 332044, at *116, 189. The unadmitted evidence that petitioners complain about here is only relevant to the special master's second, alternative analysis; it has no bearing on the first. Because petitioners have not objected to the primary holding of unreliability, based only upon the publicly available information, any error made by the special master in not requiring the disclosure of Dr. Rima's underlying data would be harmless.

However, the special master did not err. First, petitioners' reliance upon the rules of evidence and civil procedure is misplaced. In most cases before the Court of Federal Claims, parties utilizing expert testimony are required to submit a written report from the expert, along

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[53] Petitioners thrice reveal their true discontent in their motion for review–in the motion's introductory material, with respect to testimony that the copy numbers were too high, and regarding evidence of the use of allelic discrimination. See Mot. 5 ("[T]he Special Master[] erred by failing to give weight to the substantial concessions by respondent's expert witnesses."), 40 ("The special master, however, either ignored or discounted this important evidence." (emphasis added)), 41 ("In this case the special master ignored and discounted petitioner[s'] direct evidence . . . ." (emphasis added)).

with, among other things, "the data or other information considered by the witness in forming" his or her opinions. RCFC 26(a)(2)(B). The expert may then testify to his or her opinions "without first testifying to the underlying facts or data, unless the court requires otherwise." Fed. R. Evid. 705. The opposing party, however, may seek the disclosure of the underlying facts or data on cross-examination. Id. Of course, these rules do not apply to proceedings in the Vaccine Program. Rather, as dictated by Congress in the Vaccine Act, "[t]here is no discovery as a matter of right," Vaccine Rule 7(a), and special masters are not "bound by common law or statutory rules of evidence," Vaccine Rule 8(b)(1). See 42 U.S.C. § 300aa-12(d)(3)(B). Acknowledging this fact, petitioners assert that the more formal rules are part of the "general framework" for evaluating and weighing expert testimony that the special master applied elsewhere in her decision. Mot. 52. They contend that because the special master applied "[Federal Rule of Evidence] 702 and the body of case law under that Rule in weighing evidence in this case," she should have also applied RCFC 26(a)(2)(B) and Federal Rule of Evidence 705. Id.; accord Oral Argument Tr. 22-24.

In her decision, the special master made only one direct reference to Federal Rule of Evidence 702:

> In courts that apply the Federal Rules of Evidence, it is doubtful that some of petitioners' expert witnesses would have withstood challenge under Daubert and Rule 702, based on their lack of qualifications to opine on the subjects at issue and the speculative and unsupported nature of their opinions. In cases filed under the Vaccine Act, where the rules of evidence do not apply, Daubert does not generally serve as a basis to exclude testimony, but rather, a framework to weigh and evaluate testimony.

Snyder, 2009 WL 332044, at *138 (referring to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)). Although she speculated how other courts might apply Federal Rule of Evidence 702 to the evidence in this case, the special master unequivocally stated that the rule did not apply in this proceeding. That does not mean, however, that all expert testimony, regardless of its reliability, must be admitted in Vaccine Program cases. Indeed, Vaccine Rule 8(b) requires that the special master, "[i]n receiving evidence, . . . must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Thus, the Federal Circuit has sanctioned the use of the Daubert factors "as a tool or framework for conducting the inquiry into the reliability of evidence." Terran ex rel. Terran v. Sec'y of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 2000);[54] see also Ryman, 65 Fed. Cl. at 40 (noting that a special

[54] Petitioners imply that it is problematic that only "one Federal Circuit decision [stated] that special masters can use the Daubert factors to evaluate the reliability of scientific evidence in the [Vaccine] Program." Mot. 19 n.43 (citing Terran, 195 F.3d at 1316). However, that "one" decision is binding precedent. See Preminger v. Sec'y of Veterans Affairs, 517 F.3d 1299, 1309 (Fed. Cir. 2008) ("A prior precedential decision on a point of law by a panel of this court is binding precedent and cannot be overruled or avoided unless or until the court sits en banc.").

master performs a gate-keeping function "when he determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon"). Unlike Federal Rule of Evidence 702, there is no analogue in the Vaccine Rules for Federal Rule of Evidence 705 or RCFC 26(a)(2)(B). Indeed, there is no right to cross-examination in Vaccine Program proceedings. 42 U.S.C. § 300aa-12(d)(2)(D). Thus, any inquiry that normally would fall under these rules would fall within the special master's discretion to conduct discovery and determine the reliability of evidence. See 42 U.S.C. § 300aa-12(d)(2)(B), -12(d)(3)(B); Vaccine Rules 7-8; Whitecotton, 81 F.3d at 1108 ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider . . . ."); Burns, 3 F.3d at 417 (noting that the special master "had wide discretion in conducting the proceedings in a case"); Doe, 76 Fed. Cl. at 338 (noting that "special masters are given an active role in determining the facts relevant to Vaccine Act petitions"). The special master found Dr. Rima's opinions to be relevant and reliable. See, e.g., Snyder, 2009 WL 332044, at *125 ("Respondent's experts carefully and persuasively explained why even Unigenetics' high copy number results were not a reliable indicator of measles virus in the samples reported."). Thus, the special master's decision not to exclude Dr. Rima's testimony for lack of underlying data was not in error.[55]

In addition, the special master's finding of waiver was well-supported. As noted above, for various, legitimate reasons, respondent was unable to file the expert reports obtained from the U.K. MMR litigation until just before the Cedillo hearing. Petitioners agreed that additional proceedings could be conducted with respect to the material obtained from the U.K. MMR litigation at a later time and indicated that they intended to request additional materials from that litigation not obtained by respondent. The three special masters and respondent agreed to join petitioners' application. Indeed, the special masters even signed a letter in support of petitioners' application. Yet, petitioners never applied to the court in the United Kingdom for the data underlying Dr. Rima's expert report and testimony. Accordingly, the special master held:

> With regard to their inability to examine any evidence underlying . . . Dr. Rima's critiques of Unigenetics laboratory's results, petitioners also waived any objection by their failure to request disclosure of such materials from the U.K. court. As the testimony . . . makes abundantly clear, voluminous materials were filed with the U.K. court regarding the laboratory's operations. Although Unigenetics is no longer in business, the U.K. court is. Given the amount of impassioned argument devoted to the petitioners' need for such materials, petitioners' failure to lodge a

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Moreover, the Federal Circuit has approvingly cited Daubert subsequent to Terran. See Andreu, by Andreu v. Sec'y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009).

[55] As respondent noted at oral argument, the arguments advanced by petitioners in support of excluding Dr. Rima's testimony would also support the exclusion of all of the test results from Unigenetics because petitioners did not submit the data underlying the test results as part of their prima facie case. See Oral Argument Tr. 50.

> request for their disclosure in the months following all three Theory 1 hearings is inexplicable. It is also waiver.

Id. at *27. Petitioners now argue that she "improperly shift[ed] the burden of discovery from the Special Masters to the petitioners." Mot. 53.

As previously noted, the Vaccine Act provides that "[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master." 42 U.S.C. § 300aa-12(d)(3)(B); accord Vaccine Rule 7(a) ("There is no discovery as a matter of right."). In the House Report supporting the original Vaccine Act, Congress explained that because it expected a special master "to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim," discovery would be at the "prerogative" of the special master. H.R. Rep. No. 99-908, at 14-15. Subsequently, in the Conference Report supporting the 1989 amendments to the Vaccine Act, Congress elaborated: "The system is intended to allow the proceedings to be conducted in what has come to be known as an 'inquisitorial' format, with the master conducting discovery (as needed), cross-examination (as needed), and investigation." H.R. Rep. No. 101-386, at 87. And, based upon the Vaccine Act's prescriptions, Vaccine Rule 7 requires a party seeking formal discovery to petition the special master "to employ any of the discovery procedures set forth in RCFC 26-37" or issue "a subpoena pursuant to RCFC 45."

Petitioners complain that although they "repeatedly asked the Special Masters to intervene to obtain the requested UK materials[, i]n every instance the Special Masters declined."[56] Mot. 53. Specifically, they aver that "since 2003," they "pursued both formal and

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[56] The special master described these requests. She explained that "[d]uring the June 8, 2007 status conference, petitioners . . . noted that they had sought release of U.K. litigation material through third party subpoenas to Merck three years earlier," but, "[a]pparently ignoring the fact that the U.K. court controlled release of the U.K. litigation materials, petitioners renewed a request for the court to subpoena Merck and other manufacturers to obtain the reports of all 65 experts in the U.K. litigation." Snyder, 2009 WL 332044, at *24 (footnote omitted). She further explained:

> Given the U.K. court's protective order on witnesses, it does not appear that Merck could have released those materials without the consent of the U.K. court, even if ordered to do so by Special Master Hastings. [Petitioners'] counsel conceded as much when he noted that their experts who were also experts in the U.K. litigation were subject to protective orders and, therefore, could not discuss their knowledge of the U.K. proceedings.

Id. at *24 n.74 (citation omitted). Then, at the Snyder hearing, petitioners' counsel "expressed his concern and willingness to do what was necessary to obtain the U.K. expert reports" and "requested that [the special master] subpoena the reports from the U.K. court." Id. at *26.

informal efforts to obtain materials relating to the UK litigation directly from the parties to that litigation, and by requesting that the Special Masters enforce those requests by order, petition to the UK courts, or subpoena. Every request was denied."[57] Id. at 54; accord Oral Argument Tr. 8 ("We litigated this issue for a couple of years, from 2003 well into 2006 . . . ."). Petitioners' argument suggests that there is some unspecified sovereign-to-sovereign agreement whereby special masters have unfettered access to all documents possessed by foreign tribunals, wherever located, even those filed under seal. This notion is simply untrue. The special master explained this to petitioners at hearing:

> I noted that the Hague Convention governed subpoenas in foreign jurisdictions,[58] and that a subpoena for a document under seal was not the normal method of obtaining [the information sought]. Once again, respondent's counsel offered to assist petitioners in obtaining any documents they sought, and stated that U.K. law allowed third parties, including private litigants, to obtain matters filed under seal.

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[57] Petitioners' attempts to obtain the U.K. MMR litigation materials prior to 2007 have little relevance to the issue at hand: whether petitioners' failure to file an application with the court in the United Kingdom for the materials underlying Dr. Rima's expert report and testimony constituted waiver. It is clear from petitioners' description that none of their pre-2007 efforts included an attempt to obtain the materials directly from the United Kingdom court.

[58] As described by the Supreme Court:

> The United States, the Republic of France, and 15 other Nations have acceded to the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters. . . . This Convention–sometimes referred to as the "Hague Convention" or the "Evidence Convention"–prescribes certain procedures by which a judicial authority in one contracting state may request evidence located in another contracting state.

Société Nationale Industrielle Aérospatiale v. U.S. Dist. Court for the S. Dist. of Iowa, 482 U.S. 522, 524 (1987) (citation omitted). The United Kingdom is one of the signatories. Id. at 524 n.1. Article 10 of the Hague Convention provides that "[i]n executing a Letter of Request the requested authority shall apply the appropriate measures of compulsion in the instances and to the same extent as are provided by its internal law for the execution of orders issued by the authorities of its own country or of requests made by parties in internal proceedings." Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, opened for signature Mar. 18, 1970, art. 10, 23 U.S.T. 2555. Article 11 provides that "[i]n the execution of a Letter of Request the person concerned may refuse to give evidence in so far as he has a privilege or duty to refuse to give the evidence . . . under the law of the State of execution." Id. art. 11. And, Article 12 provides that "[t]he execution of a Letter of Request may be refused only to the extent that . . . the State addressed considers that its sovereignty or security would be prejudiced thereby." Id. art. 12.

Snyder, 2009 WL 332044, at *26 (footnote added). Although the special master had complete control over the discovery process in this case, such control does not extend to compelling a court in a foreign jurisdiction to unseal documents. Petitioners acknowledged this fact at oral argument before the undersigned. See Oral Argument Tr. 8 ("[T]he special masters consistently said that they did not have the power on their own to obtain that information from the United Kingdom jurisdiction."), 12 (agreeing that the special masters lacked "the authority or the ability to move Justice Keith to produce those materials"). Accordingly, the special master did not improperly shift the burden to petitioners to obtain the documents from the U.K. MMR litigation–there was no burden to shift because the special master could not have obtained the evidence sought by petitioners in the first instance. And, because she gave petitioners every opportunity to obtain those documents, and expressly supported their application, petitioners' failure to apply to the court in the United Kingdom for the documents is sufficient for a finding of waiver. For all of the foregoing reasons, the court finds that the special master did not abuse her discretion in considering Dr. Rima's testimony absent the underlying data. Petitioners' fifth numbered objection is rejected.

F. Petitioners' Sixth Numbered Objection: Refusing to Consider Significant Posthearing Evidence

In their sixth numbered objection, petitioners contend that the special master erred in denying their motion for reconsideration, and, accordingly, refusing to consider the "new" evidence submitted with their motion, which was "not available at the time of the hearing in June of 2007 . . . ." Mot. 54-55. Specifically, they claim:

> This new evidence significantly affects many critical aspects of the special master's decision. Given the familiarity of the special master with the science in Colten's case, and given the limited nature of this new evidence, the special master should have been able to quickly decide if this new evidence is worthy of consideration. In light of the significance of the evidence, and in light of the impact of this decision upon thousands of autistic children in the Program, her failure to do so was an abuse of discretion.

Id. at 55.

The special master's March 16, 2009 ruling on petitioners' motion for reconsideration contains the salient facts. Petitioners filed their motion on Friday, March 13, 2009, at 6:02 p.m. Almost all of the "new" evidence submitted with the motion was published before she rendered her decision.[59] The deadline for filing such a motion, pursuant to Vaccine Rule 10(c), was March

[59] The special master commented: "Petitioners' failure to request to reopen the evidentiary record to present the . . . 'new evidence' prior to the decision issuing in this case says

5, 2009. And, pursuant to Vaccine Rule 23, the thirty-day filing deadline for any motion for review fell on Monday, March 16, 2009. The special master declared that petitioners' motion was untimely,[60] that "the last minute nature of the filing and petitioners' failure to demonstrate good cause for that untimely filing" necessitated a denial of the motion, and that even if she considered the merits of the motion, petitioners "failed to demonstrate that the interest of justice would be served by granting their motion . . . ." Ruling 2-3.

Special masters have "wide discretion in conducting the proceedings in a case." Burns, 3 F.3d at 417; accord 42 U.S.C. § 300aa-12(d)(3)(B); Vaccine Rule 8(a); Doe, 76 Fed. Cl. at 338-39; Sword, 44 Fed. Cl. at 190. This discretion "applies to petitions for reconsideration of rulings, and proffers designed to supplement the factual record after the record is closed." Sword, 44 Fed. Cl. at 190. The court finds no abuse of discretion here.[61] The special master held that petitioners failed to comply with the requirements of the Vaccine Rules, and even had they so complied, the evidence was insufficient to result in the granting of their motion. Both of these reasons for the special master's denial of petitioners' motion were well within her discretion to make. As the Court of Federal Claims commented in Sword:

> [T]his Court will not aid a party who seeks to present additional evidence after his initial effort proves unpersuasive. . . .
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> . . . What trial attorney worth his or her salt would not try a case a bit differently once counsel knew what the fact-finder found important within the

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volumes about the value of this evidence to any causation decision and speaks loudly about the motivation for the untimely filing." Ruling Mot. Recons. ("Ruling") 2 n.2, Mar. 16, 2009.

[60] In so ruling, the special master remarked: "The untimely filing of this motion for reconsideration, on the eve of the deadline for filing a motion for review of my decision, suggests a thinly veiled effort by petitioners' counsel to obtain additional time for filing their motion for review, while placing additional evidence before the court." Ruling 2; see also id. at 2 n.4 (noting that if a special master grants a motion for reconsideration, he or she must withdraw the underlying decision, rendering it "void for all purposes, including the triggering of the 30 day period for filing an appeal").

[61] For this reason, the court has disregarded all of the references and citations in petitioners' motion for review to the evidence submitted with their motion for reconsideration. See, e.g., Mot. 35 n.52, 44, 48-49.

> body of evidence? But fairness does not require that we accede to this all-[too]-human desire. In fact, under the circumstances it would impose an undue burden to delay the resolution of this case any further.

Id. at 190-91. The court therefore rejects petitioners' sixth numbered objection.

G. Petitioners' Seventh Numbered Objection: Decision Not in Accordance With the Law

In their seventh, and final, numbered objection, petitioners argue that "[t]he special master improperly applied Daubert to the experts' conclusions and improperly ignored the teachings of recent Federal Circuit decisions." Mot. 56. Prior to addressing petitioners' argument, a brief summary of the relevant Federal Circuit precedent is instructive.

1. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if a petitioner proves, by a preponderance of evidence, all of the elements set forth in 42 U.S.C. § 300aa-11(c)(1), and if there is not a preponderance of evidence that the illness is not due to factors unrelated to the administration of the vaccine.[62] A petitioner in the Vaccine Program can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1). In this case, petitioners did not attempt to prove a Table injury because even though the relevant vaccines are listed on the Table, Colten's alleged injuries are not. Thus, petitioners proceeded on a causation-in-fact theory.

To establish a prima facie case when proceeding on a causation-in-fact theory, a petitioner must "prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). "[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show 'a medical theory causally connecting the vaccination and the injury.'" Id. at 1352-53 (quoting Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). In other words, "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury,'" id. at 1353 (quoting Grant, 956 F.2d at 1148), and "[t]his 'logical sequence of cause and effect' must

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[62] Subsection (c)(1) requires, among other things, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table ("Table"); (2) that the vaccine was received in the United States or in its trust territories; (3) that the injured person either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine that resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. 42 U.S.C. § 300aa-11(c)(1).

be supported by a sound and reliable medical or scientific explanation," Knudsen, by Knudsen v. Sec'y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing Daubert, 509 U.S. at 579; Jay v. Sec'y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Grant, 956 F.2d at 1148); see also 42 U.S.C. § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). However, medical or scientific certainty is not required. Knudsen, 35 F.3d at 548-49; Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

In Althen, the Federal Circuit articulated a three-part test, based on this prior precedent, explaining what a petitioner must show to prove causation-in-fact under the Vaccine Act:

> [Petitioner]'s burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. The first prong seeks to demonstrate whether "'the vaccine(s) at issue cause the type of injury alleged.'" Pafford, 451 F.3d at 1355-56 (quoting the decision of the special master as recited by the trial court).

The second prong requires a petitioner to show "that the vaccine was the 'but for' cause of the harm," id. at 1356, or, in other words, "'that the vaccine actually caused the alleged symptoms in [the] particular case,'" id. (quoting the decision of the special master as recited by the trial court); see also Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1326 ("'A logical sequence of cause and effect' means what it sounds like–the claimant's theory of cause and effect must be logical."). A petitioner is not required to provide "conclusive evidence in the medical literature linking" the vaccine to the injury alleged. Andreu, 569 F.3d at 1378; see also id. at 1379 ("'[I]n a field bereft of complete and direct proof of how vaccines affect the human body,' a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery." (quoting Althen, 418 F.3d at 1280)); Capizzano, 440 F.3d at 1325 ("[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen . . . ."). Moreover, the "medical records and medical opinion testimony" of treating physicians can be "probative," because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1278); accord Andreu, 569 F.3d at 1376.

The third prong, although probative, is insufficient, standing alone, to prove causation. Althen, 418 F.3d at 1278. Moreover, the prong "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." De Bazan, 539 F.3d at

1352. "If a claimant satisfies the first and third prongs of the Althen standard, the second prong can be met through medical opinion testimony." Andreu, 569 F.3d at 1375 (citing Capizzano, 440 F.3d at 1326). All three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355.

Once a petitioner has established a prima facie case, the burden shifts to respondent to show, by a preponderance of the evidence, that the injury was caused by factors unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995) ("The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused by factors unrelated to the administration of the vaccine . . . . If the Secretary fails to rebut, the claimant is entitled to compensation." (citation & internal quotation marks omitted)); De Bazan, 539 F.3d at 1352 ("Once the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact, the burden shifts to the government to prove '[by] a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition.'" (quoting 42 U.S.C. § 300aa-13(a)(1)(B))). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley, 991 F.2d at 1575. Regardless of whether the burden ever shifts to respondent, the special master may consider the evidence presented by respondent in determining whether the petitioner has established a prima facie case. See De Bazan, 539 F.3d at 1353 ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.").

2. Improper Use of Daubert

Petitioners first make the blanket accusation that the special master "improperly applied Daubert to the experts' conclusions," rather than to the methods employed by the experts.[63] Mot.

[63] Elsewhere in their motion for review, petitioners commented that it was "fundamentally unfair" for the special master to apply Daubert to find "virtually all of Colten's evidence unreliable." Mot. 11. When determining fundamental fairness to the parties, there is no direct correlation between the sheer volume of evidence offered and amount of evidence that must be admitted and ultimately credited at hearing. Merely because a party offers a huge volume of evidence does not mean that the special master is duty bound to accept any of that material as persuasive. It is hardly unusual for diametrically opposed expert views to be admitted as evidence at hearing. However, it is up to the trier of fact to weigh and credit that evidence. As the Court of Federal Claims has explained, "[s]imply because a witness is found qualified to testify as an expert does not mean that the trier of fact must accept his testimony." Ultimo, 28 Fed. Cl. at 151.

Here, petitioners, in effect, offer a numbers challenge to the manner in which the special master weighed and credited evidence. According to petitioners, because a large amount of their

56. They do not expand on this allegation to show how error was committed or provide any citation to the portions of the decision containing the alleged misapplication. Thus, petitioners place the burden on the court to divine precisely how the special master's application of Daubert might have been improper.

Daubert requires a trial judge to perform "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." 509 U.S. at 592-93. Moreover, "[t]he inquiry . . . is, . . . a flexible one. Its overarching subject is the scientific validity–and thus the evidentiary relevance and reliability–of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." Id. at 594-95 (footnote omitted). The Supreme Court later acknowledged, however, that "conclusions and methodology are not entirely distinct from one another. " Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). It further explained:

> Trained experts commonly extrapolate from existing data. But nothing in . . . Daubert . . . requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Id. Viewed in its totality, "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 142 (1999).

The special master described her general approach in applying Daubert to the evidence in the instant case:

> The special master determines the reliability and plausibility of the expert medical opinions offered and the credibility of the experts offering them. Not all evidence carries equal weight with a trier of fact. A medical opinion on causation may be based on factually incorrect medical histories or it may be offered by someone without the necessary training, education, or experience to offer a reliable opinion. An expert's opinion may be unpersuasive for a variety of

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evidence was not accepted by the special master, that fact, in and of itself, establishes that she committed error. Taking petitioners' view to its logical conclusion, in order to demonstrate fundamental fairness, a special master would be required to admit and credit a certain, unspecified percentage of the evidence proffered at hearing. Thus, the notion of fundamental fairness would be reduced to nothing more that an examination of percentage rate for the admission and acceptance of evidence, i.e., a quota. Petitioners' unsound construct is contrary to established law. At hearing, a special master must determine not only the admissibility of evidence, but how to weigh and credit that evidence, even if it is offered by a properly credentialed expert witness.

> reasons. Courts, whether they deal with vaccine injuries, medical malpractice claims, toxic torts, or accident reconstruction, must base their decisions on reliable evidence. Daubert, 509 U.S. at 594-96. Daubert provides a useful framework for evaluating scientific evidence in Vaccine Act cases. Terran v. Sec'y, HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999) . . . . See also Ryman v. Sec'y, HHS, 65 Fed. Cl. 35, 40 (2005) (special master performs gatekeeping function when he "determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon").

Snyder, 2009 WL 332044, at *30. She further explained that "[u]nder the Vaccine Act, a special master may determine the reliability of a medical theory by considering the framework established by Daubert" and that "Daubert requires that an opinion be supported by something more than subjective belief; it must be grounded 'in the methods and procedures of science.'" Id. at *194. She continued:

> Daubert provided a non-exhaustive list of factors for a court to consider in evaluating a proffer of expert testimony: (1) whether a theory has or can be tested; (2) whether the theory has been subjected to peer review and publication (a relevant, but not dispositive consideration); (3) the known or potential error rate of a technique; and (4) whether the theory enjoys general acceptance in the relevant scientific community. Kumho Tire added that a trial judge must ensure "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."
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> . . . .
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> The Ninth Circuit applied an additional factor to the analysis of an expert's opinion . . . . The circuit court considered whether the matters the expert proposed to testify about flowed from research conducted independently of involvement in the litigation in question, because this factor provides objective proof that the research was conducted for scientific purposes.

Id. at *138-39; accord id. at *194. Moreover, as noted by the special master, "[i]n his opening statement in Snyder, petitioners' counsel appeared to agree that Daubert's non-exhaustive list of factors to consider in determining the admissibility of an expert's opinion were appropriate factors to consider in weighing and evaluating evidence in this case." Id. at *9 n.33; accord Oral Argument Tr. 54, 60-61.

The special master initially applied Daubert and its progeny in her evaluation of the parties' expert witnesses. She explained:

> My evaluation of the quality of the testimony and the qualifications of the witnesses offering that testimony is based, in part, on the factors the Supreme Court set forth in Daubert . . . and Kumho Tire Company. . . . It is also based on my personal observations of each witness who testified. I emphasize that my decision is not based solely on the experts' relative qualifications; although that is an important factor, it is not, standing alone, determinative. A qualified expert with lesser qualifications may offer an opinion that, for a variety of reasons, is more persuasive than that of a more qualified expert testifying on behalf of an opposing party.

Snyder, 2009 WL 332044, at *9 (footnote omitted). First, with respect to Dr. Kennedy, she noted that his one publication on the measles vaccine was authored for the sole purpose of litigation. Id. (citing Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1993)). She then noted concerns with Dr. Kinsbourne's intellectual rigor and frequency of testifying in Vaccine Program cases. Id. at *11 (citing Kumho Tire Co., 526 U.S. at 152), 12 (citing Daubert, 43 F.3d at 1317). Finally, she noted that "two courts ha[d] refused, based on Daubert, to permit [Dr. Bradstreet] to testify as an expert witness in cases alleging that vaccines cause or contribute to [autism spectrum disorder]." Id. at *21 (citing Redfoot v. B.F. Ascher & Co., No. C 05-2045 PJH, 2007 WL 1593239, at *12 (N.D. Cal. June 1, 2007); Easter v. Aventis Pasteur, Inc., 358 F. Supp. 2d 574 (E.D. Tex. 2005)).

Next, the special master applied Daubert in evaluating petitioners' proffered medical theory. She first concluded that petitioners' theory, as described by Dr. Kinsbourne, was not generally accepted or supported by peer-reviewed medical literature.[64] Id.; see also id. at *87-93 (discussing the scientific basis of Dr. Kinsbourne's theories). She also concluded that the "key piece of evidence" supporting petitioners' theory–the "test results from a laboratory that is no longer in existence and whose practices and methods were seriously flawed"–was unreliable. Id. at *195; accord id. at *116 ("The Unigenetics laboratory had several of the hallmarks of unreliability noted in Daubert. It was established, primarily, if not solely, for the purpose of supporting the claimants in the U.K. MMR litigation. Its results were not reproducible by independent investigators, and its quality control problems were so pervasive that they suggested gross negligence, if not outright scientific fraud."); see also id. at *116-35 (discussing the reliability of the Unigenetics laboratory). Couching that conclusion in the language of Daubert, the special master explained that "Unigenetics' rate of error was unacceptable." Id. at *195. Accordingly, the special master found that petitioners had not established, by a preponderance of evidence, a biologically plausible, reliable, or reputable medical theory. Id. at *194.

The court finds no error in the special master's application of the framework suggested by Daubert. Federal Circuit precedent explicitly permits a special master to evaluate scientific

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[64] Petitioners' contention that the sole basis for the special master's dismissal of their proffered medical theory was that it was not generally accepted by the medical community, Mot. 19, lacks merit.

evidence using the Daubert factors. See Terran, 195 F.3d at 1316; cf. Andreu, 569 F.3d at 1379 (citing Daubert with approval). Here, the special master considered all of the relevant evidence submitted by both parties, using the Daubert factors only to determine the reliability of that evidence and, hence, the weight it should be assigned. Indeed, by allowing all relevant evidence to be admitted into the record, regardless of its reliability, the special master was actually being quite generous to petitioners. As the special master noted throughout her decision, petitioners' expert witnesses compared unfavorably to respondent's expert witnesses in many respects: their credentials,[65] their demeanor, how forthcoming they were at hearing, and the quality of their testimony.[66] See, e.g., Snyder, 2009 WL 332044, at *8-22 & nn.34-65 (describing the credentials, expertise, and testimony of all of the expert witnesses).

Accordingly, to the extent that petitioners are complaining that the special master's use of the Daubert factors resulted in a failure to consider their evidence, they are mistaken. Rather, the special master evaluated all of the evidence presented by both parties and determined that the science behind petitioners' theory was lacking. Contrary to petitioners' contention that the investigation into the link between the MMR vaccine, along with all thimerosal-containing vaccines, and autism spectrum disorders "is 'bereft' of science," Mot. 11, the record demonstrates that there is an abundance of science in this area–just not science that supports petitioners' position. The special master's application of Daubert was in accordance with the law.

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[65] The special master noted several instances of résumé padding, as well as several occasions where petitioners' experts testified outside their stated expertise. See, e.g., Snyder, 2009 WL 332044, at *10 ("Dr. Kennedy . . . tended to offer opinions outside his areas of expertise."), 14 ("Doctor Byers' credibility was not enhanced by several instances of 'resume padding.'"), 15 (noting that Dr. Byers "strayed into matters beyond her expertise"), 17 (noting that while Dr. Krigsman's curriculum vitae listed four publications, only one was a published article, and that the other three consisted of an unpublished article, a "slide presentation," and a "poster and abstract of preliminary data").

[66] The special master indicated that while the testimony of petitioners' experts was often sincere and heartfelt, it was, at times, speculative. See, e.g., Snyder, 2009 WL 332044, at *12 ("Doctor Corbier presented as an earnest and sincere witness, albeit one whose expert opinions were heavily laced with generalities, speculation, and conjecture."), 17 ("Dr. Krigsman's testimony about autistic enterocolitis as a diagnostic entity was speculative and unsupported by the weight of the evidence."). Daubert clearly envisions the exclusion of evidence that amounts to nothing more than speculation. See 509 U.S. at 590 (noting that scientific evidence must be "more than subjective belief or unsupported speculation"); see also Gen. Elec. Co., 522 U.S. at 146 ("[N]othing in . . . Daubert . . . requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert."); Perreira ex rel. Perreira v. Sec'y of HHS, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it." (citing Daubert, 509 U.S. at 579)).

3. Causation

Petitioners further contend that they have established a prima facie case pursuant to the three-part test set forth in Althen and that respondent failed to establish an alternative cause. Id. at 59. Their argument, in its entirety, is as follows:

> Has Colten satisfied the Althen factors? Clearly, he has a medical theory. His evidence is strong that the MMR vaccine is capable of causing a wide variety of brain injuries, including autism. Next, there was a logical sequence of cause and effect between his MMR vaccine and the injury. He was healthy, received an MMR vaccine, and as his treating physicians attest, he was never again the same. There is no question that his symptoms first occurred within an appropriate time after the MMR vaccine. This fact is supported by Colten's medical records and by the respondent's expert Dr. Griffin. It is even supported by the Vaccine Injury Table that lists "5-15" days after the MMR as the appropriate time frame for the onset of symptoms of brain damage. See 42 U.S.C. Section 300aa-14.

Id. Such a perfunctory argument requires little attention.

As noted above, the special master found under the first prong of the Althen test that petitioners' medical theory was not reliable. See Snyder, 2009 WL 332044, at *194-95. Under the second prong, she found that there was no "logical connection between Colten's vaccinations and his medical condition" because of the unreliability of the test results indicating the presence of measles virus in Colten's CSF and the absolute necessity of the presence of measles virus for petitioners' theory of causation. Id. at *195-97. She also found that the medical records and medical opinion testimony of Dr. Bradstreet, one of Colten's treating physicians, were unsupportive of causative link.[67] Id. With respect to the third prong, the special master found, based on the objective evidence in Colten's medical records, that the onset of Colten's speech

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[67] After briefing had concluded on petitioners' motion for review, but prior to oral argument, the Federal Circuit issued its decision in Andreu, reaffirming its prior holdings that the testimony of treating physicians is "'quite probative' since 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" 569 F.3d at 1375 (quoting Capizzano, 440 F.3d at 1326, and citing Althen, 418 F.3d at 1279-80; Zatuchni v. Sec'y of HHS, 69 Fed. Cl. 612, 623 (2006)). However, there is nothing in Andreu that mandates that the testimony of a treating physician is sacrosanct–that it must be accepted in its entirety and cannot be rebutted. Indeed, the Federal Circuit did not disturb its prior holdings concerning the deference accorded the special masters' findings of facts. In any event, petitioners did not raise Andreu's discussion of treating physicians at oral argument; in fact, they do not contend in their motion for review that the special master improperly considered the evidence from any of Colten's treating physicians in this case, including the sole testifying treating physician–Dr. Bradstreet. Accordingly, an analysis of Andreu as it relates to the testimony of treating physicians is unnecessary here.

problems began between the ages of seventeen and nineteen months (approximately June through August of 1998), over a month after his April 23, 1998 MMR vaccination. Id. at *197-98. Finally, she concluded that because petitioners had failed to establish a prima facie case of entitlement, the burden of proving an alternative cause never shifted to respondent. Id. at *198.

The court finds no error in the special master's findings. The special master's conclusion that petitioners did not present a biologically plausible medical theory is clearly supported by the record. She found that the various aspects of petitioners' theory were not scientifically sound and that the lynchpin of their theory was wholly unreliable. See id. at *87-93 (petitioners' theory), 116-35 (Unigenetics' reliability). Next, the special master's conclusion that petitioners had not established a logical sequence of cause and effect is also supported by the record. As noted above, petitioners' theory of causation depended upon, among other things, Colten's immune system being damaged by the MMR vaccine (but not thimerosal-containing vaccines), the persistence of the measles virus in Colten's body, Colten's development of inflammatory bowel disease, and the presence of the measles virus in Colten's brain. The special master found that petitioners had demonstrated none of these necessary elements by a preponderance of the evidence. See id. at *185-86 (dysregulated immune system), 186-87 (inflammatory bowel disease), 188-92 (persistence and presence of the measles virus). Further, the special master's conclusion that the onset of Colten's symptoms did not occur within a biologically acceptable time period following the MMR vaccination is supported by the record. She found that based on the medical records, the onset of Colten's symptoms did not occur at the time suggested by petitioners. Id. at *197-98. Given that petitioners had not established any of the prongs of the test set forth in Althen, the special master correctly concluded that the burden of proving an alternative cause never shifted to respondent. See Bradley, 991 F.2d at 1575.

Petitioners' complaints with the special master's decision amount to nothing more than dissatisfaction with the weight she assigned to the evidence. Yet, as the court has repeated throughout this opinion, the special master is accorded great deference in determining how much weight to assign to the evidence in the record. She was the one who read all of the medical records, expert reports, and medical literature, and heard all of the testimony, placing her in the best position to ascertain whether petitioners established a prima facie case of causation. The special master exercised her discretion appropriately here and her decision was not contrary to law. The court thus rejects petitioners' seventh numbered objection.

H. Petitioners' Allegation of Bias

The court has addressed all of petitioners' numbered objections, finding them to be without merit. However, petitioners lodge other complaints about the special master's conduct that despite their lack of merit, cannot be ignored. Specifically, petitioners advance the remarkable complaint that "the special master abandoned her obligation to impartially weigh the evidence. . . . [I]nstead, the special master inappropriately assumed the respondent's role as protector of the integrity of vaccines." Mot. 6. Petitioners later elaborate:

> During the past decade, the publicity afforded the issue of whether vaccines can cause autism has been intense. . . . [D]ue to this publicity, . . . the special master feared that a finding in [petitioners'] favor would drive down immunization rates. For this reason, to protect the integrity of vaccines, Colten's case, a so-called "test" case, was treated far differently than other vaccine program petitioners. First, after thousands of other autistic children had filed claims, and after years of intense public controversy over the vaccine/autism connection, the respondent was permitted to present the opinions of seventeen experts to defeat Colten's claim. In so doing, the special master treated Colten far differently than other petitioners.[68] In addition, disregarding the Federal Circuit's recent decisions in Althen and Capizzano, the special master instead invoked Daubert and found virtually all of Colten's evidence unreliable. For her to do so . . . was fundamentally unfair. [Petitioners were] entitled to equal treatment.

Id. at 11; accord id. at 17 (complaining that the special master did not afford petitioners "the 'fundamental fairness' required by the Vaccine Rules" due to the "extraordinary publicity" given the three Theory 1 test cases and, as a result, Colten "was sacrificed to protect the integrity of vaccines"[69]). To reinforce their attack on the special master, petitioners reiterate their allegations of bias, charging:

> [T]he special master ignored [petitioners'] considerable, albeit circumstantial, evidence that a persisting vaccine-strain measles virus caused [his inflammatory bowel disease] and autism. . . . [S]he did so because of the intense national publicity this case has received. . . . [S]he did so to assure the American public that vaccines are safe. She did so because she views her role as a protector of the integrity of our nation's vaccines. This, however, is the role of the respondent, not a special master.

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[68] Although petitioners are complaining about the number of expert witnesses presented by respondent here, they later insist that "they did not–and do not–object to the number of presentations of the many highly qualified scientists retained by the respondent." Mot. 27. This is obviously not the case. See also id. at 5 ("[T]he respondent presented the opinions of seventeen (17!) expert witnesses . . . ." (exclamation in the original)), 19 (arguing that the special master "simply accepted the conclusions of the respondent's seventeen experts"). Relatedly, the court notes that there is no evidence that the special master limited either party in the number of expert witnesses they could present.

[69] At oral argument, the court asked petitioners' counsel–Mr. Powers–whether he "stood by [his] statement that Colten was 'sacrificed' to protect the integrity of vaccines." Oral Argument Tr. 33. He answered in the negative, subsequently stating: "I am willing . . . , more removed in time from preparing that brief, if I wrote it again, I would probably change the words that I used." Id. at 34.

. . . .

> . . . . [T]he special master, to protect vaccine integrity in a very public case, chose to impose upon [petitioners] an unattainable standard of proof. To protect the vaccine's integrity she rejected all of petitioner's credible evidence and simply accepted the conclusions of the respondent's seventeen experts, denying [petitioners] the fundamental fairness required by the Vaccine Rules, ignored Congress'[s] intent in establishing the Vaccine Program, and rejected the Federal Circuit's interpretation of that intent.

Id. at 19-21. Finally, at oral argument, petitioners attempted to justify their charge of bias by arguing that it was fundamentally unfair for the special master to admit the purportedly unreliable evidence from Dr. Bustin and Dr. Rima and, thereafter, "allow[] the credibility of those witnesses to substitute for the reliability of those witnesses on key issues . . . ." Oral Argument Tr. 30-31.

Petitioners' charge–that the special master feared a public backlash against vaccines if she ruled in their favor–is preposterous. There is not a shred of evidence to support petitioners' claim;[70] it rests solely on petitioners' speculation. Merely because the special master found that petitioners did not carry their burden of proof does not diminish her integrity or render her decision unsupported. Claims of error by a losing party against a decision maker are hardly unusual, but should be grounded in reality. There is an enormous chasm between disagreement with a judicial officer's findings of fact and conclusions of law and the accusation that the judicial officer is, in essence, intellectually dishonest. An allegation of bias raises ethical concerns, not errors in judgment (i.e., legal or factual errors). Although petitioners appeared to understand this distinction at oral argument, they maintained that the special master was biased against them by unfairly "shift[ing] the burden of discovery" and "weighing . . . the evidence . . . ." Id. at 32-33. However, alleged errors of this nature are grounded on purportedly mistaken evidentiary rulings, factual findings, and legal conclusions, not bias. And, the court has already held that it identified no legal or factual error in the special master's decision.

Indeed, it is abundantly clear from her decision that the special master took great care in considering all of the evidence in the record–whether presented by petitioners or respondent–and applying the appropriate legal standards in evaluating that evidence. As the Court of Federal Claims stated in Ultimo:

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[70] In their motion for review, petitioners provide no citations to the record or other evidence to support their claims. They do quote a speech made by the Chief Special Master in a nonlitigative context, Mot. 20, but such reliance is improper because the speech is not in the record and there is no indication that anything in that speech reflects the views of Special Master Vowell. In light of petitioners' failure to support their bias claim in their motion for review, they sought to provide some clarification to their allegations at oral argument, as discussed in the text above.

> This sort of personal attack on the [special master] is highly inappropriate, contentious, and unpersuasive. . . . Petitioner . . . accuses the [special master] of subverting the intent of Congress in establishing the Program. The court will not condone such frivolous, unsubstantiated accusations. Accordingly, the court finds that petitioner's . . . objection is completely without merit. Petitioner is forewarned that any repetition of such groundless accusations may cause the court to entertain sanctions against petitioner and petitioner's counsel pursuant to RCFC 11.

28 Fed. Cl. at 153.

III. CONCLUSION

As the special master's decision makes clear, Colten, and by extension, his family, have dealt with significant adversity for many years, and, like the special master, the court is very sympathetic to their circumstances. However, the court cannot be ruled by emotion and base its determination solely upon the adversity endured by petitioners' family. Moreover, it is not the task of this court to determine whether vaccines cause autism or other neurodevelopmental disorders. Rather, the court must decide whether the special master, considering the record as a whole, rendered a decision that was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. She did not. Her decision was entirely rational and fully supported by the record. Thus, the court **DENIES** petitioners' motion for review. Pursuant to Vaccine Rule 30(a), the clerk is directed to enter judgment in accordance with this decision.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge